

Attachment B

Enforcement Data
July 1- October 1, 2006

California State Board of Pharmacy

Citation and Fine Statistics

July 1, 2006 – December 31, 2006

263 citations have been issued so far this fiscal year

Total dollar amount of fines issued since July 1, 2006
\$ 914,950.00

Total dollar amount of fines collected
\$ 166,517.00*

*This amount reflects payment of the citations issued before July 1, 2006.

The average number of days from date case is
opened until a citation is issued is **165**

Average number of days from date citation is
issued to date citation is closed is **68**

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
263	41	5	67	31	39	11	9	2

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
8	4	2	5	3	3	3	8	1

*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations for the second quarter of 2006/2007 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	25%	1716 - Variation from prescription	20%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	10%
4339 - Non-pharmacist acting as manager, compounding, dispensing, or furnishing drugs	5%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	12%	1716/1761 - Variation from Rx / Erroneous Rx	6%
4322 - Misdemeanor or infraction: false representation to secure license for self or others; false representation of licensure	5%	1716/1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	6%	4115(e) - Pharmacy technician license required	5%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	5%	4115(e) - Pharmacy technician license required	3%	1715 - Self-assessment of a pharmacy by the pharmacist-in-charge	3%
1716/1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	4%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	2%	1761 - Erroneous or uncertain prescription	3%
1707.3 - Duty to review drug therapy	3%	1793.7(d) - Requirements for pharmacies employing pharmacy technicians - pharmacy technician must wear identification...	2%	4059 - Furnishing dangerous drugs or devices prohibited without a prescription	3%
1716/1761 - Variation from Rx / Erroneous Rx	3%	4081(a)- Records of dangerous drugs kept open for inspection	2%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	3%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	2%	1715(a) Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	3%
4081(a)- Records of dangerous drugs kept open for inspection	3%	4126.5(a) - Furnishing Dangerous Drugs by Pharmacy; Authorized recipients	2%	1717(c) - Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing...	3%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	3%	4163(b) - Unauthorized Furnishing by Manufacturer or Wholesaler; Manufacturer or pharmacy may not sell, trade or transfer dangerous drug at wholesale without a pedigree	2%	4163 (b)/4126.5 (a) - Unauthorized Furnishing by Manufacturer or Wholesaler; Manufacturer or pharmacy may not sell, trade or transfer dangerous drug at wholesale without a pedigree/ Furnishing Dangerous Drugs by Pharmacy; Who pharmacy may furnish	3%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were ten office conferences held so far this fiscal year

Number of requests	135	Number scheduled	135
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Number appeared	85*	Number Postponed	28**
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*Please note on three occasions unscheduled citations were heard with a related case at office conference.
 **Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	23
Failed to appear	3

Office Conference results held between July 1, 2006 and December 31, 2006

Total number of citations affirmed	46
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Decision	Total citations	Total dollar amount reduced
Modified	19	\$2,750.00
Dismissed	14	\$1,625.00
Reduced to Letter of Admonishment	1	\$0.00

Please note Two cases from SOC, are pending a decision

Board of Pharmacy Enforcement Statistics

Fiscal Year 2006/2007

Workload Statistics **July-Sept Oct-Dec Jan-Mar Apr-June Total 06/07**

Complaints/Investigations

Initiated	378	373			751
Closed	412	266			678
Pending (at the end of quarter)	671	922			922

Cases Assigned & Pending (by Team)

Compliance Team	103	85			85
Drug Diversion/Fraud	106	125			125
Mediation Team	85	57			57
Probation/PRP	56	65			65
Enforcement	94	186			186

Application Investigations

Initiated	68	97			165
Closed					
Approved	3	14			17
Denied	2	3			5
Total*	6	17			23
Pending (at the end of quarter)	98	178			178

Citation & Fine

Issued	141	121			262
Citations Closed	172	124			296
Total Fines Collected	\$75,815.00	\$90,701.70			\$166,516.70

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2006/2007

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 06/07**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	35	20			35
Pleadings Filed	24	22			46
Pending					
Pre-accusation	59	52			52
Post Accusation	86	69			69
Total	149	128			128
Closed**					
Revocation					
Pharmacist	1	4			5
Pharmacy	1	3			4
Other	9	14			23
Revocation, stayed; suspension/probation					
Pharmacist	1	2			3
Pharmacy					0
Other					0
Revocation, stayed; probation					
Pharmacist	1	1			2
Pharmacy					0
Other					0
Suspension, stayed; probation					
Pharmacist					0
Pharmacy					0
Other					0
Surrender/Voluntary Surrender					
Pharmacist	3	7			10
Pharmacy		5			5
Other	1	4			5
Public Repraisal/Reprimand					
Pharmacist					0
Pharmacy					0
Other					0
Cost Recovery Requested	\$40,239.00	\$142,128.75			\$182,367.75
Cost Recovery Collected	\$21,104.66	\$39,650.49			\$60,755.15

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics

Fiscal Year 2006/2007

Workload Statistics

July-Sept Oct-Dec Jan-Mar Apr-June Total 06/07

Probation Statistics

Licenses on Probation

Pharmacist	93	100			100
Pharmacy	5	6			6
Other	14	13			13
Probation Office Conferences	9	7			16
Probation Site Inspections	92	41			133
Probationers Referred to AG for non-compliance	3	0			3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 12/31/06)

Program Statistics

In lieu of discipline	0	0			0
In addition to probation	2	4			6
Closed, successful	1	4			5
Closed, non-compliant	1	0			1
Closed, other	0	1			1
Total Board mandated Participants	50	54			54
Total Self-Referred Participants*	26	30			30
Treatment Contracts Reviewed	43	46			89

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of December 31, 2006.



California State Board of Pharmacy

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

January 24, 2007

To: Board Members

Subject:: Demonstration by IBM of an Electronic Pedigree System to Track Prescription
Medicine from Manufacturers through Wholesalers to Pharmacies

During this portion of the Board Meeting, IBM will provide a presentation on technology to perform electronic tracking of medicine.

The presentation will be by Craig Asher, Co-Chair, EPCglobal, EPCIS Work Group. Mr. Asher will speak on both the technology and the standards development activities.

There are no other information at this time to share with you in advance of the meeting.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Goal 5: Achieve the board's mission and goals.

Outcome: An effective organization

Objective 5.1	Obtain 100 percent approval for identified program needs by June 30, 2011.
Measure:	Percentage approved for identified program needs
Tasks:	<ol style="list-style-type: none"> <p>Review workload and resources to streamline operations, target backlogs and maximize services.</p> <p><i>1st Qtr 2006: Monthly statistics of workload reviewed to identify backlogs.</i></p> <p><i>Sept. 2006: Supervising Inspector Meeting where management reviews all cases under investigation.</i></p> <p><i>Dec. 2006: Licensing processes converted to department's applicant tracking system (ATS).</i></p> <p><i>2nd Qtr 2006: Monthly statistics of workload reviewed to identify backlogs.</i></p> <p>Develop budget change proposals to secure funding for needed resources.</p> <p><i>July 2006: Budget Change Proposals submitted for Administration review.</i></p> <p><i>Jan 2007: Governor's proposed budget for 2007/08 contains two BCPs:</i></p> <ol style="list-style-type: none"> <i>(1) \$576,000 for recruitment and retention differential of \$2,000 per month for each board inspector/pharmacist.</i> <i>(2) restoration of three positions lost during the hiring freezes of the early 2000s (receptionist, complaint analyst, licensing technician).</i> <p>Perform strategic management of the board through all committees and board activities.</p> <p><i>Aug. 2006: Strategic plan approved at July 2006 Board Meeting. Staff redesigns quarterly reporting format for committee reports to the board.</i></p> <p><i>Oct. 2006: Quarterly report of each committee's progress toward strategic goals reported to board.</i></p> <p><i>Jan. 2007: Quarterly report of each committee's progress toward strategic goals reported to board.</i></p> <p>Manage the board's financial resources to ensure fiscal viability and program integrity.</p> <p><i>Oct. 2006: Committee and board review budget figures for revenue and expenditures for 2005/06 and 2006/07. A fund condition report is also reviewed; possible fee increase is possibly needed to take effect July 1, 2008.</i></p> <p><i>Oct. 2006: Committee and board review budget figures for revenue and expenditures for 2005/06 and 2006/07. New BCPs and salary adjustments for all staff continue to increase annual expenditures. A fund condition report is also reviewed; possible fee increase is possibly needed to take effect July 1, 2008.</i></p>



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

January 24, 2007

To: Board Members

Subject : Discussion and Possible Action Regarding Proposed Medicaid Program:
Prescription Drugs, Proposed Rule 42 CFR Part 447

The Board of Pharmacy's mandate is consumer protection. Typically issues involving reimbursement to pharmacies that will be paid by third party payors or by MediCal (or federally Medicaid) are issues the board leaves to professional associations.

Currently out for comment is a proposed federal rule (42 CFR Part 447) that would change how reimbursement is made to pharmacies providing Medicaid services – and consequently in California, MediCal services. A number of materials describing this process are provided following this cover page.

At the request of several parties, Board President Powers has added this item to the agenda as a discussion item.

There has been concern expressed to the board that if reimbursement is made to pharmacies for MediCal services according to the new process, some (perhaps many) pharmacies will discontinue service to MediCal patients.

Lack of access by MediCal patients to pharmacies that will provide medicine to them will be a problem that affects consumer protection.

During this portion of the board meeting, the board will have an opportunity to evaluate whether it wishes to submit comments stating the concern that the proposed change in reimbursement may have a negative impact on continued consumer access to Medicaid prescriptions. If so, these comments are due by February 20, 2007.

[Click here to forward this to a friend or colleague.](#)

Source: NCPA Executive Update
1/19/07

[IMAGE]

January 19,
2007

[IMAGE]

**Other posts
on
Executive
Update
on the Web**

- Legislative
Agenda for
the New
Congress
[more »](#)

- Incentives
for
Medicaid
Generic
Dispensing
[more »](#)

- Proposed
Regulation
on Medicaid
Cuts Issued
[more »](#)

- Polls and
Perceptions
[more »](#)

- Medication
Adherence
Disconnect
[more »](#)

- Proving
Our Value
[more »](#)

- Why
Wal-Mart's
Tactics
Matter

[IMAGE] **Comments for CMS on AMP**

Dear Colleague,

You've already heard a lot from me about Medicaid, generic drugs, and AMP, and you're going to be in for much more. This is a critical issue for community pharmacy in 2007. As things now stand, Medicaid on July 1 will begin reimbursing for generic drugs with a new FUL under a new definition of AMP. As required by the Deficit Reduction Act, the FUL will be a **ceiling** of 250% the of AMP for the class of generic drugs at issue.

That doesn't sound too bad, **if** the AMP covers our actual acquisition cost. But what is the AMP for any drug? We don't know. The figures are reported to CMS by manufacturers, who have a vested interest in keeping them as low as possible because they are the basis for the rebates they must pay to Medicaid.

AMP was never intended to be part of a pharmacy reimbursement formula. Trying to serve two masters, rebates and reimbursement, will hurt community pharmacy badly. CMS won't tell us what any AMPs are, even with the manufacturers' names redacted.

Still, the agency expects us to submit specific examples of the impact of the proposal on pharmacy. It's like going to a restaurant where your menu doesn't have any prices, the guest's does, and he insists that you pick up the tab. You know you're going to get stuck□you just don't know how badly.

While sources in the generic industry won't give us real world examples, they do tell us the definition of AMP proposed in the regulation to be issued in final form by July 1 would cover about half of our average acquisition costs at best.

The period for us to comment on the proposed regulation ends Feb. 20. Very soon we will be sending out talking points to all state associations, wholesalers, buying groups, and members asking them to incorporate these comments into their remarks on the proposed definition.

- Community Pharmacy's Post-Election Scorecard

[more »](#)

- NCPA Challenges CVS to

Clean Up PBM

Abuses

[more »](#)

- Good Things Come in Threes?

[more »](#)

- AWP Lawsuit

[more »](#)

- Viva Las Vegas

[more »](#)

- The Good Guys Win One

[more »](#)

We want everyone to convey the same message, which the talking points will provide, and we need a heavy volume of comments as well. As much as CMS be can influenced (and we are not overly optimistic), quality and quantity both count. We also will be filing in-depth comments ourselves, which I will be sharing with you.

Even without knowing the verdict from CMS, most likely to come in April or May, NCPA and Coalition for Community Pharmacy Action (CCPA) will be following a two-track strategy: a legislative fix of the AMP definition through

Congress, and state legislative or regulatory action to increase dispensing fees. Neither track is prone to speedy decisions.

Hopefully, the cost of dispensing study done through CCPA by the global accounting firm Grant Thornton can persuade lawmakers of the gravity of community pharmacy's financial situation. The coalition is not ready to release it publicly yet, but it will show that the average cost nationwide of dispensing a prescription is between \$9-\$11 and will contain COD information for Medicaid prescriptions as well as state COD figures.

We will be making the point that an accurate dispensing fee must reflect the true costs of preparing and dispensing the prescription, assuring its appropriate use, store operations and overhead, staffing costs, and a reasonable profit margin to offset pharmacy service costs.

As I said before, you'll be hearing more from me because this issue is not going to go away soon. I hope CMS will be hearing from you, too.

Regards,
Bruce Roberts, RPh.



Federal Register

Friday,
December 22, 2006

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Prescription Drugs;
Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2238-P]

RIN 0938-AO20

Medicaid Program; Prescription Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. The DRA requires the Secretary of Health and Human Services to publish a final regulation no later than July 1, 2007. In addition, we would add to existing regulations certain established Medicaid rebate policies that are currently set forth in CMS guidance. This rule would bring together existing and new regulatory requirements in one, cohesive subpart.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 20, 2007.

ADDRESSES: In commenting, please refer to file code CMS-2238-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2238-P, P.O. Box 8015, Baltimore, MD 21244-8015.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention:

CMS-2238-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kimberly Howell, (410) 786-6762 (for issues related to the determination of average manufacturer price and best price).

Yolanda Reese, (410) 786-9898 (for issues related to authorized generics).

Madlyn Kruh, (410) 786-3239 (for issues related to nominal prices).

Marge Watchorn, (410) 786-4361 (for issues related to manufacturer reporting requirements).

Gail Sexton, (410) 786-4583 (for issues related to Federal upper limits).

Christina Lyon, (410) 786-3332 (for issues related to physician-administered drugs).

Bernadette Leeds, (410) 786-9463 (for issues related to the regulatory impact analysis).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully

considering issues and developing policies. You can assist us by referencing the file code CMS-2238-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

[If you choose to comment on issues in this section, please include the caption "Background" as the beginning of your comments.]

A. Introduction

Under the Medicaid program, States may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal financial participation (FFP) in State expenditures for these drugs. In order for payment to be made available under section 1903 for certain drugs, manufacturers must enter into a Medicaid drug rebate agreement as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formula for calculating rebate payments, and requirements for States with respect to covered outpatient drugs.

This proposed rule would implement sections 6001(a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA), Pub. L. 109-171 (Feb. 8, 2006). It also would codify those parts of section 1927 of the Act that pertain to requirements for drug manufacturers' calculation and reporting of average

manufacturer price (AMP) and best price, and it would revise existing regulations that set upper payment limits for certain covered outpatient drugs. This proposed rule would also implement section 1903(i)(10) of the Act, as revised by the DRA, with regard to the denial of FFP in expenditures for certain physician-administered drugs. Finally, the proposed rule would address other provisions of the drug rebate program, to the extent those provisions are affected by the DRA.

The Medicaid Drug Rebate Program was established by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Pub. L. 101-508 (Nov. 5, 1990) and subsequently modified by the Veterans Health Care Act of 1992 (VHCA), Pub. L. 102-585 (Nov. 4, 1992) and the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66 (Aug. 10, 1993). These provisions were implemented primarily through the national drug rebate agreement (56 FR 7049 (Feb. 21, 1991)) and other informal program releases, which provide standards for manufacturer reporting and rebate calculations. The statutory changes that affect the provisions of this proposed rule are described below.

B. Changes Made by the Deficit Reduction Act of 2005

Section 6001(a) of the DRA amends section 1927(e) of the Act to revise the formula CMS uses to set Federal upper limits (FULs) for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the average manufacturer price (AMP) (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

Section 6001(b) of the DRA amends section 1927(b)(3) of the Act to create a requirement that manufacturers report certain prices to the Secretary monthly. It also requires the Secretary to provide AMP to States on a monthly basis beginning July 1, 2006 and post AMP on a Web site at least quarterly. We are aware of concerns that the AMPs released to the States beginning July 1, 2006, will not reflect changes to the definition of AMP made by the DRA and proposed in this rule. While we made the AMPs available to the States beginning July 1, 2006, States should keep these data confidential in accordance with section 1927(b)(3)(D) of the Act. Section 6001(b) of the DRA revises these confidentiality provisions to permit States to use AMP to calculate payment rates; however, these confidentiality amendments are not effective until January 1, 2007. This six-month period will give the States a

chance to review the AMP data and revise their systems to address the DRA amendments.

Section 6001(c) of the DRA modifies the definition of AMP to remove customary prompt pay discounts extended to wholesalers from the AMP calculation and requires manufacturers to report these customary prompt pay discounts to the Secretary. It requires the Inspector General of the Department of Health and Human Services (IG) to review the requirements for, and the manner in which, AMP is determined and submit to the Secretary and Congress any recommendations for changes no later than June 1, 2006. Finally, it requires the Secretary to promulgate a regulation that clarifies the requirements for, and the manner in which, AMP is determined no later than July 1, 2007, taking into consideration any IG recommendations.

Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal price to the Secretary for calendar quarters beginning on or after January 1, 2007. It also specifies the entities to which nominal price applies. It limits the merely nominal exclusion to sales at nominal prices to the following: A covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

Section 6001(e) of the DRA amends section 1927 of the Act to provide for a survey of retail prices and State performance rankings. These provisions are not addressed in this proposed rule.

Section 6001(f) of the DRA makes minor amendments to section 1927(g) of the Act which are self-implementing.

Section 6001(g) of the DRA provides that the amendments in section 6001 are effective on January 1, 2007, unless otherwise noted.

Section 6002 of the DRA amends section 1903(i)(10) of the Act by prohibiting Medicaid FFP for physician-administered drugs unless States submit the utilization data described in section 1927(a) of the Act. It also amends section 1927 of the Act to require the submission of utilization data for physician-administered drugs.

Section 6003(a) of the DRA amends section 1927(b)(3)(A) of the Act to require manufacturers to include within

AMP and best price all of its drugs that are sold under a new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA) when they report AMP and best price to the Secretary.

Section 6003(b) of the DRA amends section 1927(c)(1)(C) of the Act to clarify that manufacturers must include the lowest price available to any entity for a drug sold under an NDA approved under section 505(c) of the FFDCA when determining best price. Section 6003(b) also amends section 1927(k) to require that in the case of a manufacturer that approves, allows, or otherwise permits any of its drugs to be sold under an NDA approved under section 505(c) of the FFDCA, the AMP shall be calculated to include the average price paid for such drugs by wholesalers for drugs distributed to the retail pharmacy class of trade. Section 6003(c) of the DRA provides that the amendments made by section 6003 are effective January 1, 2007.

The statutory provisions in the DRA that affect the Medicaid Drug Rebate Program, as well as the regulatory provisions we are proposing to implement the program, are discussed in greater detail in the section entitled "Provisions of the Proposed Regulations" below.

C. Notice of Proposed Rulemaking Published September 19, 1995

On September 19, 1995, CMS (then the Health Care Financing Administration) published a notice of proposed rulemaking (NPRM) in the **Federal Register** (60 FR 48442 (Sept. 19, 1995)). The purpose of the 1995 NPRM was to propose regulations pertaining to the Medicaid Drug Rebate Program and to address the national rebate agreement (56 FR 7049 (Feb. 21, 1991)). On August 29, 2003, CMS finalized two of the provisions in the 1995 NPRM through a final rule with comment period (68 FR 51912). These regulations require manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also provided that manufacturers should report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data are due. On November 26, 2004, we published final regulations (69 FR 68815) that require a manufacturer to retain pricing data for 10 years from the date the manufacturer reports that data to CMS and for an additional time frame where the manufacturer is the subject of an audit or government investigation. Due to the time that has elapsed since publication of the 1995 NPRM and

changes in the prescription drug industry, we do not plan to finalize the other provisions of that proposed rule, and any comments on the 1995 NPRM are outside the scope of this proposed rule. This proposed rule does not address the entire Medicaid Drug Rebate Program, but focuses primarily on the provisions of the DRA that address the Medicaid Drug Rebate Program.

II. Provisions of the Proposed Regulations

Basis and Purpose of Subpart I—Section 447.500

This subpart would implement specified provisions of sections 1927, 1903(i)(10), and 1902(a)(54) of the Act related to implementation of the DRA. It would include requirements related to State plans, FFP for drugs, and the payment for covered outpatient drugs under Medicaid. In this rule, we also propose to move the existing Medicaid drug provisions in the Federal regulations from subpart F to subpart I of 42 CFR part 447.

Definitions—Section 447.502

This section of the rule would include definitions of key terms used in 42 CFR part 447, subpart I. We propose to use definitions from several sources, including the Act, Federal regulations, program guidance, and the national rebate agreement. We invite the public to provide comments on the terms we have chosen to define as well as the proposed definitions described below.

Bona fide service fee would mean a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug would mean a single source or innovator multiple source drug.

Bundled sale would mean an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased

separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.

Consumer Price Index “Urban (CPI-U)” would be defined the same as it is in the national rebate agreement, except we would replace “U.S. Department of Commerce” with “U.S. Department of Labor” to reflect that the Department of Labor is now responsible for updating the CPI-U. Therefore, the term CPI-U would mean the index of consumer prices developed and updated by the U.S. Department of Labor. For purposes of this subpart, it would be the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Dispensing fee would be defined similarly to how it is defined for the Medicare Part D program in 42 CFR 423.100 in light of some of the parallels of Part D to Medicaid. We are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee. The formula is consistent with our regulation that defines estimated acquisition costs which give States flexibility to determine EAC. However, consistent with a recommendation made by the Office of the Inspector General (OIG) in its report, “Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,” (A-06-06-00063) May 2006, we encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

Dispensing fee would be defined as the fee which—

(1) Is incurred at the point of sale and pays for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in

checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Innovator multiple source drug would be defined based on the definition in section 1927(k)(7)(A)(ii) of the Act. We would also use the definition from the national rebate agreement. Innovator multiple source drug would mean a multiple source drug that was originally marketed under an original NDA approved by the Food and Drug Administration (FDA). It would include a drug product marketed by any cross-licensed producers or distributors operating under the NDA and a covered outpatient drug approved under an NDA, Product License Approval, Establishment License Approval or Antibiotic Drug approval. We believe this definition is consistent with our understanding of the drug rebate statute and section 6003 of the DRA which includes within the definition those drugs which often receive a certain amount of patent protection and/or market exclusivity.

Manufacturer would be defined based on the definition in section 1927(k)(5) of the Act and the national rebate agreement. It would also mirror the current definition of manufacturer used by Medicare in the regulations regarding manufacturer's average sales price (ASP) data. For purposes of the Medicaid program, manufacturer would be defined as any entity that possesses legal title to the NDC for a covered drug or biological product and—

(a) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(b) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesaler of drugs or a retail pharmacy licensed under State law.

(c) With respect to authorized generic products, the term "manufacturer" will also include the original holder of the NDA.

(d) With respect to drugs subject to private labeling arrangements, the term "manufacturer" will also include those entities that do not possess legal title to the NDC.

Multiple source drug is currently defined in Federal regulations at section 42 CFR 447.301. We propose removing the definition from that section and revising the definition to reflect the DRA amendments to section 1927 of the Act. We would define the term multiple source drug to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.fda.gov/cder/orange/default.htm> or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For purposes of this subpart, it would mean the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code).

National rebate agreement is described in section 1927 of the Act. Section 1927(b) of the Act outlines the terms of the rebate agreement, including reporting timeframes, manufacturer responsibilities, penalties, and confidentiality of pricing data. We propose that the national rebate agreement would continue to be defined as the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price would be defined as it is in the national rebate agreement. We propose incorporating this definition in this rule because it is the standard presently used in the Medicaid program and the Medicare Part B program, and is similar to that used by the

Department of Veterans Affairs (DVA) in administering the Federal Supply Schedule (FSS). Nominal price would mean a price that is less than 10 percent of AMP in the same quarter for which the AMP is computed.

Rebate period is defined in section 1927(k)(8) of the Act as a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under the national rebate agreement. The Medicaid Drug Rebate Program currently operates using a calendar quarter for the rebate period. While AMPs would be reported monthly for purposes of calculating FULs and for release to States, we can find no evidence in the legislative history of the DRA that Congress intended to change the definition of rebate period. Therefore, we would define rebate period as a calendar quarter.

Single source drug is defined in section 1927(k)(7)(A)(iv) of the Act as a covered outpatient drug which is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It is further defined in the national rebate agreement as a covered outpatient drug approved under a Product License Approval, Establishment License Approval, or Antibiotic Drug Approval. We propose to define the term single source drug as it is defined in the statute and the national rebate agreement.

Determination of Average Manufacturer Price—Section 447.504

Background

Prior to the DRA, section 1927(k)(1) of the Act specified that the AMP with respect to a covered outpatient drug of a manufacturer for a rebate period is the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts.

The national rebate agreement (56 FR 7049 (Feb. 21, 1991)) further specifies that:

- Direct sales to hospitals, health maintenance organizations (HMOs) and wholesalers, where the drug is relabeled under that distributor's national drug code number, and FSS prices are not included in the calculation of AMP;
- AMP includes cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid;
- AMP is calculated as net sales divided by the number of units sold,

excluding free goods (*i.e.*, drugs or any other items given away, but not contingent on any purchase requirements), and

- Net sales means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid.

Consistent with these provisions, it has been our policy that in order to provide a reflection of market transactions, the AMP for a quarter should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

AMP should be adjusted for bundled sales (as defined above) by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations. The aggregate discount is allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Where discounts are offered on multiple products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle. The average unit price means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Provisions of the DRA

Section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers, effective January 1, 2007. Section 6001(c)(3) of the DRA requires the OIG to review the requirements for and manner in which AMPs are determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA requires the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendations.

OIG Recommendations on AMP

In accordance with 6001(c)(3) of the DRA, the OIG issued its report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005," (A-06-06-00063), in May 2006. In this report, the OIG recommended that CMS:

- Clarify the requirements in regard to the definition of retail pharmacy class of trade and treatment of pharmacy

benefit manager (PBM) rebates and Medicaid sales and

- Consider addressing issues raised by industry groups, such as:
 - Administrative and service fees,
 - Lagged price concessions and returned goods,
 - The frequency of AMP reporting,
 - AMP restatements, and
 - Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

- Issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- Encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

We address these recommendations as we discuss provisions of this proposed rule in the section below.

Definition of Retail Pharmacy Class of Trade and Determination of AMP

We recognize that there have been concerns expressed regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes in the drug marketplace, and the introduction of newer business practices such as payment of services fees. We also realize that in light of the DRA amendments, AMP will serve two distinct purposes: For drug rebate liability and for payments. For the purpose of determining drug rebate liability, drug manufacturers would generally benefit from a broad definition of retail pharmacy class of trade which would include entities that purchase drugs at lower prices and which would lower rebate liability. Including these lower prices would decrease the AMP, decreasing manufacturers' rebate liability. The retail pharmacy industry might benefit from a narrow definition of retail pharmacy prices that would be limited to certain higher priced sales given that, in light of the DRA amendments, States might use AMP to calculate pharmacy payment rates. Excluding low-priced sales would increase AMP, increasing, in all likelihood, manufacturers' rebate payments. The pharmacy industry believes that mail order pharmacies and nursing home pharmacies (long-term care pharmacies) pay less for drugs than retail pharmacies (e.g., independents and chain pharmacies), and thus the inclusion of such prices would lower AMP below the price paid by such retail pharmacies.

The statute mandates that, effective January 1, 2007, the Secretary use AMP when computing FULs. For this purpose, we would exclude certain outlier payments (see our discussion in the FULs section for a more complete description of outlier exclusions). The statute also requires that AMP be provided to States monthly and be posted on a public Web site. While there is no requirement that States use AMPs to set payment amounts, we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail pharmacy class of trade. We considered several options to define what prices should be included in AMP. We considered including only prices of sales to retail pharmacies that dispense drugs to the general public (e.g., independent and chain pharmacies) in retail pharmacy class of trade and removing prices to mail order pharmacies, nursing home pharmacies (long-term care pharmacies), and PBMs. This definition would address the retail pharmacy industry's contentions that an AMP used for reimbursement to retail pharmacies should only reflect prices of sales to those pharmacies which dispense drugs to the general public.

The exclusion of prices to mail order pharmacies, nursing home facilities (long-term care facilities), and PBMs would substantially reduce the number of transactions included in AMP. Removal of these prices would simplify AMP calculations for manufacturers because it is our understanding that certain data (e.g., PBM pricing data) are difficult for manufacturers to capture. In addition, removal of these prices would address differing interpretations of CMS policy identified by the OIG and the Government Accountability Office (GAO) due to the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP. However, such a removal would not be consistent with past policy, as specified in manufacturer Releases 28 and 29 (http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp#TopOfPage), would likely result in a higher AMP, and would result in an increase in drug manufacturers' rebate liabilities.

We also considered not revising the entities included in the retail pharmacy class of trade. However, this would not address the issues identified by the OIG in its report, "Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug

Manufacturers to Better Implement the Program," (A-06-91-00092), November 1992 and GAO in its report "Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States," (GAO-05-102), February 2005.

We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we would exclude from AMP the prices of sales to nursing home pharmacies (long-term care pharmacies) because nursing home pharmacies do not dispense to the general public. We would include in AMP the prices of sales and discounts to mail order pharmacies. We considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under similar terms and conditions. However, given our belief that such prices are simply another form of how drugs enter into the retail pharmacy class of trade, we have decided to maintain these prices in the definition. We note that even were we to incorporate this change, retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for some manufacturer price concessions. CMS seeks public comment on the inclusion of all mail order pharmacy prices in our definition of retail pharmacy class of trade for purposes of inclusion in the determination of AMP.

We recognize that a major factor contributing to the determination of AMP is the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990. We are considering how PBM rebates, discounts, or other price concessions should be recognized for purposes of AMP calculations.

A GAO report "Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States," (GAO-05-102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the recently issued OIG report, "Determining Average

Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005," (A-06-06-00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates. This report says that manufacturers treat rebates and fees paid to PBMs in the calculation of AMP in three different ways. Specifically they found that manufacturers (1) did not subtract rebates or fees paid to PBMs from the AMP calculation; (2) subtracted the rebates or fees paid to PBMs; or (3) subtracted a portion of the PBMs rebates or fees from the AMP calculation.

In developing this proposed rule, we considered including all rebates, discounts and other price concessions from PBMs in the determination of AMP. We also considered excluding rebates, discounts and other price concessions from PBMs in the determination of AMP.

One of the most difficult issues with PBM discounts, rebates, or other price concessions is that manufacturers contend that they do not know what part of these discounts, rebates, or other price concessions is kept by the PBM for the cost of its activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part, if any, that entity passes on to pharmacies. Despite the difficulties of including certain PBM rebates, discounts or other price concessions in AMP, excluding all of these price concessions could result in an artificial inflation of AMP. For this reason, we propose to include PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP; however, we invite comments on whether this proposal is operationally feasible.

As discussed more fully below, we have proposed that PBM rebates and price concessions that adjust the amount received by the manufacturer for drugs distributed to the retail pharmacy class of trade should be included in the calculation of AMP. We acknowledge that manufacturers have a variety of arrangements with PBMs and thus invite comments on all aspects of our proposal as explained below.

The rebate agreement defines AMP to include cash discounts and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid to the manufacturer for drugs distributed to the retail pharmacy class of trade. As noted in Release 28 and reiterated in Release 29, manufacturers have developed a myriad of arrangements

whereby specific discounts, chargebacks, or rebates are provided to PBMs which, in turn, are passed on to the purchaser. Those releases recognize that certain prices provided by manufacturers to PBMs should be included within AMP calculations. In accordance with those releases, our position has been that PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement. We are concerned, however, that this position may unduly exclude from AMP certain PBM prices and discounts which have an impact on prices paid to the manufacturer.

We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer. We are interested in comments on this proposal, including the comments on the operational difficulties of including such PBM arrangements within AMP calculations.

We recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade; however, in light of our understanding of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer. We invite comments on this definition and whether AMP should be calculated to include all adjustments that affect net drug prices.

We acknowledge that there are many PBM/manufacturer arrangements. To the extent manufacturers are offering rebates, discounts, or other price concessions to the PBM that are not bona fide service fees, we propose that these lower prices should be included in the AMP calculations. We request comments on the operational difficulties of tracking these rebates, discounts, or chargebacks provided to a PBM for purposes of calculating AMP and on the inclusion of all such price concessions in AMP. Specifically, we solicit comments on the extent to which CMS should or should not define in regulation which rebates, discounts, or price concessions provided to PBMs should be included in AMP and how best to measure these. Also, we solicit public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price adjustments are captured and included in the determination of AMP.

Finally, we request comments on any other issues that we should take into account in making our final decisions. These include, but may not be limited to, possible Federal and State budgetary impacts (our savings estimates assumed no budgetary impacts as generic drugs are rarely, if ever, subject to PBM price adjustments in this context); possible future evolution in industry pricing and management practices (e.g., growth of "preferred" generic drugs); and possible impacts on reimbursement for brand name drugs under Medicaid. We are generally interested in comments on how and to what extent PBMs act as "wholesalers." We propose to incorporate the explicitly listed exclusions in section 1927 of the Act, and in the national rebate agreement, which are direct sales to hospitals, HMOs/managed care organizations (MCOs), wholesalers where the drug is relabeled under that distributor's NDC and FSS prices.

The specific terms we propose to clarify and the proposed clarifications follow.

Retail Pharmacy Class of Trade: We propose to include in the definition of retail pharmacy class of trade any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public (e.g., retail, independent, chain and mail order pharmacies), except as otherwise specified by the statute or regulation (such as, HMOs, hospitals).

PBM Price Concessions: We proposed to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade.

Customary Prompt Pay Discounts: Prior to the DRA, neither the statute nor the national rebate agreement defined customary prompt pay discounts. The DRA revises the definition of AMP to exclude customary prompt pay discounts extended to wholesalers; however, it does not revise or define customary prompt pay discounts. We propose to define customary prompt pay discounts as any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date.

Treatment of Medicaid Sales: The OIG recommended that we should address whether AMP should include Medicaid prices of sales; i.e., prices of sales where the end payer for the drug is the Medicaid program. In its May 2006 report, the OIG noted confusion on this

issue and recommended that we clarify that these prices of sales are to be included in AMP. It is our position that these sales are included in AMP because they are not expressly excluded in the statute. In this proposed rule, we would also clarify that prices to State Children's Health Insurance Program Title XIX (SCHIP) through an expanded Medicaid program are covered under the provisions of section 1927 of the Act and generally subsumed in Medicaid sales. As a general matter, Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, Medicaid sales are determined by the entities that are actually in the sales chain and because Medicaid reimburses pharmacies for drugs for Medicaid beneficiaries, integrated into the chain of sales otherwise included in AMP.

In this proposed rule, we would clarify that the units associated with Medicaid sales should be included as part of the total units in the AMP calculation. We have proposed that AMP be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity excluded by statute or regulation. Therefore, we would clarify that rebates paid to States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included.

In this proposed rule, we also propose to clarify how the prices of sales to State Children's Health Insurance Program Title XXI (SCHIP) non-Medicaid expansion programs should be treated. Like the Medicaid program, SCHIP non-Medicaid expansion programs do not directly purchase drugs. Because such programs are not part of the Medicaid program, they are not covered under the provisions of section 1927 of the Act. As with Medicaid sales, these sales are included in AMP to the extent they concern sales at the retail pharmacy class of trade. Therefore, these sales should not be backed out of the AMP calculation to the extent that such sales are included within sales provided to the retail pharmacy class of trade. Rebates and units associated with those sales should also be included in the calculation of AMP.

Treatment of Medicare Part D sales: We would clarify that the treatment of

prices of sales through a Medicare Part D prescription drug plan (PDP), a Medicare Advantage prescription drug plan (MA-PD), or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals should be included in the AMP calculation. Like the Medicaid program, PDPs and MA-PDs do not directly purchase drugs, but are usually third party payers. As with Medicaid sales, these sales are included in AMP to the extent they are sales to the retail pharmacy class of trade. Therefore, we believe these prices of sales should not be backed out of the AMP. Rebates paid by the manufacturer to the PDP or MA-PD should be included in the calculation of AMP.

SPAP price concessions: In this proposed rule, we also propose to clarify how the prices to State pharmaceutical assistance programs (SPAPs) should be treated. Like the Medicaid program, PDPs, and MA-PDs, SPAPs do not directly purchase drugs, but are generally third-party payers. As with Medicaid sales, these sales are included in AMP to the extent the sales are to an entity included in the retail pharmacy class of trade. Therefore, we propose that SPAP sales should not be backed out of the AMP calculation. Rebates paid by the manufacturer to the SPAP should be included in the calculation of AMP.

Prices to other Federal Programs: We propose that any prices on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in subsection 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; and any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal government are excluded from the calculation of AMP. We propose that the prices to these entities should be excluded from AMP because the prices to these entities are not available to the retail pharmacy class of trade.

Administrative and Service Fees: Current Medicaid drug rebate policy is that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, should be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP. The OIG has

noted in its report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005," (A-06-06-00063), May 2006, that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor. Some believe that these fees should not be included in AMP because the manufacturer does not know if the fees act to reduce the price paid by the end purchasers. Others believe such fees should be included in the calculation, which would reduce AMP because they serve as a price concession. For the same reason as for sales to PBMs, we propose that all fees except fees paid for bona fide services should be included in AMP. We propose that bona fide service fees means fees paid by a manufacturer to an entity, which represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. Medicare Part B also adopted this definition in its final rule with comment period that was published on December 1, 2006 (71 FR 69623-70251) that implemented the ASP provisions enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We are not proposing to define fair market value. However, CMS invites comments from the public regarding an appropriate definition for fair market value.

Direct Patient Sales: In response to manufacturers' questions, CMS has stated previously that covered outpatient drugs sold to patients through direct programs should be included in the calculation of AMP. These sales are usually for specialty drugs through a direct distribution arrangement, where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as the storage, delivery and billing of the drug. Some manufacturers have contended that direct patient sales for covered outpatient drugs sold by a manufacturer through a direct distribution channel should not qualify for inclusion in the calculation of AMP because the Medicaid rebate statute and the national rebate agreement do not address covered outpatient drugs that are not sold to wholesalers and/or not distributed in the retail pharmacy class of trade. We believe that the distributor is acting as

a wholesaler and these sales are to the retail pharmacy class of trade. In light of this, we propose in this regulation that these sales and the rebates associated with these sales to patients through direct programs would be included in AMP. CMS invites comments from the public on this proposed policy.

Returned Goods: Current Medicaid Drug Rebate Program policy is that returned goods are credited back to the manufacturer in either the quarter of sale or quarter of receipt. This has caused difficulty for some manufacturers when these returns have substantially reduced AMP in a quarter or resulted in a negative AMP. In light of these concerns, we propose to exclude returned goods from the calculation of AMP when returned in good faith. CMS considers that goods are being returned in good faith when they are being returned pursuant to manufacturer policies which are not designed to manipulate or artificially inflate or deflate AMP. The Medicare Part B program excludes returned goods from the calculation of ASP. The exclusion of returned goods will allow the manufacturer to calculate and report an AMP that is more reflective of its true pricing policies to the retail pharmacy class of trade in the reporting period. It lessens the administrative burden and problems associated with allocating the returned goods back to the reporting period in which they were sold, as well as eliminating artificially low, zero or negative AMPs that may result from these adjustments.

Manufacturer Coupons: In this proposed rule, we propose to clarify how manufacturer coupons should be treated. The treatment of manufacturer coupons has been problematic for CMS as well as some manufacturers. In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of AMP. We believe that the redemption of coupons by the consumer directly to the manufacturer is not included in the retail pharmacy class of trade. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP. CMS invites comments from the public on this proposed policy.

Future Clarifications of AMP: Based on past comments from the GAO and the OIG and recommendations of the OIG in its May 2006 report on AMP, we believe that we need to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace for the sale of drugs. We plan to address future

clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed.

Requirements for Average Manufacturer Price

To implement the provisions set forth in sections 6001 and 6003 of the DRA related to AMP, we propose a new § 447.504. In § 447.504(a), we propose a revised definition of AMP and clarify that AMP is determined without regard to customary prompt pay discounts extended to wholesalers. In § 447.504(b), we propose to define average unit price. In § 447.504(c), we propose to define customary prompt pay discount. In § 447.504(d), we propose to define net sales. In § 447.504(e), we propose to define retail pharmacy class of trade. In § 447.504(f), we propose to define wholesaler. In § 447.504(g), we would describe in detail the sales, rebates, discounts, or other price concessions that must be included in AMP. In § 447.504(h), we would describe the sales, rebates, discounts, or other price concessions that must be excluded from AMP. In § 447.504(i), we would provide further clarification about how manufacturers should account for price reductions and other pricing arrangements which should be included in the calculation of AMP.

Determination of Best Price—Section 447.505

Prior to the DRA, section 1927(c)(1)(C) of the Act provided that manufacturers must include in their best price calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturers during the rebate period to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States except for those entities specifically excluded by statute. Excluded from best price are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices used under an SPAP; any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and prices to a Medicare Part D PDP, an MA-PD, or a qualified retiree prescription drug plan for

covered Part D drugs provided on behalf of Part D eligible individuals.

The statute further specifies that:

- Best price includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates (other than rebates under section 1927 of the Act), which reduce the price paid;
- Best price must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package;
- Best price must not take into account prices that are merely nominal in amount.

Consistent with these provisions and the national rebate agreement, it has been our policy that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

Best price should be adjusted for any bundled sale. The drugs in a “bundle” do not have to be physically packaged together to constitute a “bundle,” just part of the same bundled transaction.

Section 1927(c)(1)(C)(ii)(I) of the Act specifies that best price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from best price.

Section 103(e) of the MMA modified the definition of best price by excluding prices which are negotiated by a PDP under part D of title XVIII of the Act, by any MA-PD plan under part C of such title with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title. Section 1002(a) of the MMA modified section 1927(c)(1)(C)(i)(I) of the Act by clarifying that inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA are exempt from best price.

Section 6003 of the DRA amended section 1927(c)(1)(C) of the Act by revising the definition of best price to clarify that the best price includes the lowest price available to any entity for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FDCA.

In accordance with our understanding of congressional intent, in this proposed rule we propose to define best price with respect to a single source drug or innovator multiple source drug of a manufacturer, including any drug sold under an NDA approved under section

505(c) of the FFDCA, as the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. It continues to be our policy that best price reflects the lowest price at which the manufacturer sells a covered outpatient drug to any purchaser, except those prices specifically exempted by law. We propose to define provider as a hospital; HMO, including an MCO or PBM; or other entity that treats individuals for illnesses or injuries or provides services or items in the provisions of health care.

As with the determination of AMP, the DRA does not establish a mechanism to clarify how best price is to be determined should new entities be formed after this regulation takes effect. We believe that we need to have the ability to clarify best price in an expedited manner in order to address the evolving marketplace for the sale of drugs. We plan to address future clarifications to best price through the issuance of program releases and by posting the clarifications on the CMS Web site as needed. Even though the DRA did not require CMS to clarify the requirements for best price, we determined that it is reasonable to propose these provisions in this proposed rule, consistent with long-standing Medicaid Drug Rebate Program policy, the MMA, and our understanding of congressional intent with respect to best price as revised by the DRA.

We propose to incorporate the explicitly listed exclusions in section 1927 of the Act, which are prices charged on or after October 1, 1992, to the IHS, the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA); any prices charged under the FSS of the GSA; any prices paid under an SPAP; any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government; and payments made by a Medicare Part D PDP, an MA-PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We propose to codify this policy and require that manufacturers exclude the prices to these entities from best price. Because best price represents the lowest price available from the manufacturer to any entity with respect to a single

source drug or innovator multiple source drug of a manufacturer, including an authorized generic, any price concession associated with that sale should be netted out of the price received by the manufacturer in calculating best price and best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We propose to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as "other arrangements" and that such adjustment should be included in the calculation of best price, except to the extent that such adjustments qualify as bona fide service fees.

Consistent with our understanding of congressional intent, we propose that best price be calculated to include all sales, discounts, and other price concessions provided by the manufacturer for covered outpatient drugs to any entity unless the manufacturer can demonstrate that the sale, discount, or other price concession is specifically excluded by statute or is provided to an entity not included in the rebate calculation. To the extent that an entity is not included in the best price calculation, both sales and associated discounts or other price concessions provided to such an entity should be excluded from the calculation. The specific terms we propose to clarify and the proposed clarification follow.

The Medicaid drug rebate agreement defines best price, in part, as the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States. We propose to codify this policy in this proposed rule.

Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers; however, we can find no evidence in the legislative history of the DRA that Congress intended to change the definition of best price to exclude customary prompt pay discounts. Therefore, we propose in this regulation to include customary prompt pay discounts in best price.

PBM Price Concessions: We recognize that a major factor contributing to the determination of best price includes the treatment of PBMs. These entities have assumed a significant role in drug distribution since the enactment of the Medicaid Drug Rebate Program in 1990.

As noted in Release 28 and reiterated in Release 29, manufacturers have developed a myriad of arrangements whereby specific discounts, chargebacks, or rebates are provided to

PBMs which, in turn, are passed on to the purchaser. In such situations where discounts, chargebacks, or rebates are used to adjust drug prices at the wholesaler or retail level, such adjustments are included in the best price calculation.

A GAO report, "Medicaid Drug Rebate Program—Inadequate Oversight Raises Concerns about Rebates Paid to States," (GAO-05-102), in February 2005, indicated that the Medicaid Drug Rebate Program does not clearly address certain financial concessions negotiated by PBMs. The GAO recommended that we issue clear guidance on manufacturer price determination methods and the definitions of AMP and best price, and update such guidance as additional issues arise.

The issue regarding PBMs was also addressed in the recently issued OIG report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005," (A-06-06-00063), in May 2006. In this report, the OIG recommended that we clarify the treatment of PBM rebates.

One of the most difficult issues with PBM discounts, price concessions, or rebates is that manufacturers contend that they do not know what part of these discounts, price concessions, or rebates are kept by the PBM for the cost of their activities and profit, what part is passed on to the health insurer or other insurer or other entity with which the PBM contracts, and what part that entity passes on to pharmacies.

Despite the difficulties of including certain PBM rebates, discounts or other price concessions in best price, excluding these price concessions could result in an artificial inflation of best price. We propose to include PBM rebates, discounts, or other price concessions for the purpose of determining best price.

To the extent manufacturers are offering PBMs rebates, discounts, or other price concessions, these lower prices should be included in the best price calculations. Therefore, where the use of the PBM by manufacturers affects the price available from the manufacturer, these lower prices should be reflected in best price calculations. We acknowledge that there are many PBM/manufacturer arrangements.

We believe that PBMs often obtain rebates, discounts, or other price concessions which adjust prices, either directly or indirectly. Unless the fees/discounts qualify as bona fide service fees (which are excluded), the PBM rebates, discounts, or chargebacks should be included in best price. We propose to consider these rebates,

discounts, or chargebacks in best price calculations. CMS invites public comment on the inclusion of certain PBM price concessions in the determination of best price. Also, we solicit public comment on how these PBM price concessions should be reported to CMS to assure that appropriate price concessions are captured and included in the determination of best price.

We propose to incorporate the explicitly listed exclusions in section 1927 of the Act and in the national rebate agreement. Because best price represents the prices available from the manufacturer for prescription drugs, best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized. We propose to consider that any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as "other arrangements" and that such an adjustment should be included in the calculation of best price. The specific terms we propose to clarify and the proposed clarifications follow.

Administrative and Service Fees: We propose that administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid Drug Rebate Program, should be included in the calculation of best price, if those sales are to an entity included in the calculation of best price. As previously discussed, the OIG has noted in its report, "Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005," (A-06-06-00063), May 2006 that confusion exists about the treatment of fees, such as service fees negotiated between a manufacturer and pharmaceutical distributor for AMP and best price. We believe that price adjustments which ultimately affect those prices which are actually available from the manufacturer should be included in best price. We propose that manufacturers should include all such fees except bona fide service fees provided at fair market value in the best price calculation.

Treatment of Medicare Part D Prices: In this proposed rule, we propose to clarify the treatment of prices which are negotiated by a Medicare Part D PDP, an MA-PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals. We propose that these prices are exempt from the best price. Section 1860D-2(d)(1)(C) of the Act specifically states that "prices negotiated by a prescription drug plan,

by an MA-PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of Part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C)." Therefore, while we propose that the prices listed above be included for the purpose of calculating AMP, we propose that prices negotiated by a PDP, an MA-PD, or a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals not be taken into account for the purpose of establishing best price.

Manufacturer Coupons: In this proposed rule, we propose to clarify how manufacturer coupons should be treated for the purpose of establishing best price. We believe that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy). In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of best price. We believe that the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invites comments from the public on this proposed policy.

Medicaid Rebates and Supplemental Rebates: Section 1927(c)(1)(C)(ii)(I) of the Act and the national rebate agreement provide that any rebates paid by manufacturers under section 1927 of the Act are to be excluded from the calculation of best price. Therefore, we propose to exclude Medicaid rebates from best price. Likewise, we consider rebates paid under CMS-authorized separate (supplemental) Medicaid drug rebate agreements with States to meet this requirement and propose that these rebates be excluded from best price. In accordance with section 1927 of the Act pertaining to the determination of best price and our understanding of congressional intent, we propose a new § 447.505. In § 447.505(a), we would provide a general definition of the term best price. In § 447.505(b), we propose to define provider. In § 447.505(c), we would specify the sales and prices which must be included in best price. In § 447.505(d), we would specify which sales and prices must be excluded from best price. In § 447.505(e), we would

further clarify the price reductions and other pricing arrangements included in the calculation of best price.

Authorized Generic Drugs—Section 447.506

Under current law, drug manufacturers participating in the Medicaid Drug Rebate Program are required to report the AMP for each covered outpatient drug offered under the Medicaid program and the best price for each single source or innovator multiple source drug available to any wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity with certain exceptions.

For purposes of the Medicaid Drug Rebate Program, an authorized generic is any drug product marketed under the innovator or brand manufacturer's original NDA, but labeled with a different NDC than the innovator or brand product. According to our reading of the statute, authorized generics are single source or innovator multiple source drugs for the purpose of computing the drug rebate and are classified based on whether the drug is being sold or marketed pursuant to an NDA. Responsibility for the rebate rests with the manufacturer selling or marketing the drug to the retail pharmacy class of trade.

This rule would implement section 6003 of the DRA. We propose to adopt the term "authorized generic" and define this term with respect to the Medicaid Drug Rebate Program, as any drug sold, licensed or marketed under a new drug application approved by the FDA under section 505(c) of the FFDCA that is marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug.

Section 6003 of the DRA amended section 1927(b)(3)(A) of the Act to include drugs approved under section 505(c) of the FFDCA in the reporting requirements for the primary manufacturer (NDA holder) for AMP and best price. We propose to interpret the language of section 6003 of the DRA to include in the best price and AMP calculations of the branded drugs, the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer (or NDA holder). We believe that to limit the applicability of this regulation to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the provision by licensing rather than selling the rights to such drugs. This is why we propose a broad definition of authorized

generic drugs rather than a more narrow definition of such drugs. We propose to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price. We welcome comments on this issue.

The secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic drug products based on utilization under its own NDC number, as required under current law. We welcome comments on these issues.

In § 447.506(a), we would define the term authorized generic drug for the purposes of the Medicaid Drug Rebate Program.

In § 447.506(b), we would require the sales of authorized generic drugs that have been sold or licensed to another manufacturer to be included by the primary manufacturer as part of its calculation of AMP for the single source or innovator multiple source drug (including all such drugs that are sold under an NDA approved under section 505(c) of the FFDCA).

In § 447.506(c), we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in sales used to determine the best price for the single source or innovator multiple source drug approved under section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary manufacturer or by a subsidiary of the brand manufacturer.

Exclusion From Best Price of Certain Sales at a Nominal Price—Section 447.508

Pursuant to the terms of the national rebate agreement, manufacturers excluded from their best price calculations outpatient drug prices below 10 percent of the AMP. The rebate agreement did not specify whether this nominal price exception applied to all purchasers or to a subset of purchasers. Medicaid has used this definition since the start of the Medicaid Drug Rebate Program and Medicare Part B also adopted it in its April 6, 2004 interim final rule with comment period (69 FR 17935) that implemented the ASP provisions

enacted in the MMA. It is also similar to the definition of nominal price in the VHCA. We propose to continue to define nominal prices as prices at less than 10 percent of the AMP in that same quarter; however, in accordance with the DRA, we further propose to specify that the nominal price exception applies only when certain entities are the purchasers.

Section 6001(d)(2) of the DRA modified section 1927(c)(1) of the Act to limit the nominal price exclusion from best price to exclude only sales to certain entities and safety net providers. Specifically, it excluded from best price those nominal price sales to 340B covered entities as described in section 340B(a)(4) of the PHSA, ICFs/MR, and State-owned or operated nursing facilities. In addition, the Secretary has authority to identify as safety net providers other facilities or entities to which sales at a nominal price will be excluded from best price if he deems them eligible safety net providers based on four factors: the type of facility or entity, the services provided by the facility or entity, the patient population served by the facility or entity and the number of other facilities or entities eligible to purchase at nominal prices in the same service area.

Section 340B(a)(4) of the PHSA defines entities covered under that provision. Covered entities include: A federally qualified health center as defined in section 1905(l)(2)(B) of the Act; an entity receiving a grant under section 340A of the PHSA; a family planning project receiving a grant or contract under Section 1001 of the PHSA (42 U.S.C. § 300); an entity receiving a grant under subpart II of part C of title XXVI of the PHSA (relating to categorical grants for outpatient early intervention services for HIV disease); a State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHSA; a black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act; a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Act; a Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988; an urban Indian organization receiving funds under the title V of the Indian Health Care Improvement Act, any entity receiving assistance under title XXVI of the PHSA (other than a State or unit of local government or an entity receiving a grant under subpart II of part C of title XXVI of the PHSA), but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; an entity receiving funds under

section 318 of the PHSA (relating to treatment of sexually transmitted diseases) or section 317(j)(2) of the PHSA (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to section 340B(a)(7) of the PHSA; a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act that (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Act or eligible for assistance under the State plan under this title, (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of the Act, and (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. We do not believe it necessary to elaborate further on these entities. We propose to define ICF/MR, for purposes of the nominal price exclusion from best price, to mean an institution for the mentally retarded or persons with related conditions that provides services as set forth in 42 CFR 440.150. Additionally, we propose to define nursing facility as a facility that provides those services set forth in 42 CFR 440.155.

The statute allows the Secretary to determine other facilities or entities to be safety net providers to whom sales of drugs at a nominal price would be excluded from best price. The Secretary's determination would be based on the four factors noted above established by the DRA. We considered using this authority to expand this exclusion to other safety-net providers. We considered proposing that we use the broader definition of safety net provider used by the Institute of Medicine (IOM). In its report, "America's Health Care Safety Net, Intact but Endangered," the IOM defines safety-net providers as "providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid and other vulnerable patients." We also considered proposing how the Secretary might use the four factors to allow the

nominal price exclusion to best price to apply to other safety net providers. However, we believe that the entities specified in the statute are sufficiently inclusive and capture the appropriate safety net providers. Therefore, we have chosen not to propose to expand the entities subject to this provision at this time. Additionally, we believe that adding other entities or facilities would have an undesirable effect on the best price by expanding the entities for which manufacturers can receive the best price exclusion beyond those specifically mandated by the DRA and lowering manufacturer rebates to the Medicaid Program. Because the statute gives the Secretary discretion not to expand the list of entities, we do not propose to do so at this time in this rule.

CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We are considering crafting further guidance to address this issue. CMS invites comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

In accordance with the provisions of the DRA, the restriction on nominal price sales shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a DVA master agreement under section 8126 of title 38, United States Code.

We propose a new § 447.508 in which we would specify those entities to which a manufacturer of covered outpatient drugs may sell at nominal price and provide for the exclusion of such sales from best price.

Requirements for Manufacturers— Section 447.510

On August 29, 2003, CMS finalized two of the provisions in the 1995 NPRM through a final rule with comment period (68 FR 51912). We required manufacturers to retain records for data used to calculate AMP and best price for three years from when AMP and best price are reported to CMS. We also required manufacturers to report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data are due. On January 6, 2004, we published an interim final rule with comment

period replacing the three-year recordkeeping requirement with a ten-year requirement on a temporary basis (69 FR 508 (Jan. 6, 2004)). We also required that manufacturers retain records beyond the ten-year period if the records were subject to certain audits or government investigations. On November 26, 2004, we published final regulations (69 FR 68815) that require that a manufacturer retain pricing data for ten years from the date the manufacturer reports that period's data to CMS. We propose to move the recordkeeping requirements at § 447.534(h) to § 447.510(f) and revise them by adding the requirement that manufacturers must also retain records used in calculating the customary prompt pay discounts and nominal prices reported to CMS.

Existing regulations at § 447.534(i) require manufacturers to report revisions to AMP and best price for a period not to exceed twelve quarters from the quarter in which the data were due. We propose to move this provision to § 447.510(b) and revise it to require manufacturers to also report revisions to customary prompt pay discounts and nominal prices for the same period.

In order to reflect the changes to AMP as set forth in the DRA, we propose allowing manufacturers to recalculate base date AMP in accordance with the definition of AMP in § 447.504(e) of this subpart. Base date AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the quarterly AMP reported to CMS and the base date AMP trended forward using the CPI—U. We propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP. We propose giving manufacturers an opportunity to submit a revised base date AMP with their data submission for the first full calendar quarter following the publication of the final rule. We propose to allow manufacturers the option to decide whether they will recalculate and submit to CMS a base date AMP based on the new definition of AMP or submit their existing base date AMP. We are giving manufacturers this option because we are aware that some manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained.

Under section 1927(b)(3)(A) of the Act and the terms of the national rebate agreement, manufacturers that sign the national rebate agreement must supply CMS with a list of all product data (e.g., date entered market, drug category of

single source, innovator multiple source, or noninnovator multiple source) and pricing information for their covered outpatient drugs. In accordance with the statute, the rule would require manufacturers to report AMP and best price to CMS not later than thirty days after the end of the rebate period.

Section 6001(b)(1) of the DRA amended section 1927(b)(3)(A)(i) of the Act by adding “month of a” before “rebate period.” Section 6003(a) of the DRA restructured section 1927(b)(3)(A)(i) of the Act. The statute, as amended by these provisions, can be read in different ways. One interpretation is that the revisions made by section 6003(a) of the DRA supersede the revisions made by section 6001(b)(1) of the DRA, effectively eliminating the requirement that manufacturers report data to CMS on a monthly basis. However, we do not believe that this reading is the better reading of the statute or consistent with congressional intent. It is unreasonable to presume that Congress would simultaneously establish and render meaningless a new provision of law and we do not propose to adopt this interpretation. Another interpretation is that the revisions made by section 6001(b)(1) of the DRA, when read with the amendments made by section 6003 of the DRA, create a new requirement that AMP, best price, and customary prompt pay discounts be reported on a monthly basis. However, there is no compelling evidence in the legislative history which indicates that Congress intended to change the rebate period from quarterly to monthly. Best price is reported to CMS quarterly for purposes of our calculation of the unit rebate amount for single source and innovator multiple source drugs. While Congress clearly intended that AMPs be reported and disclosed to States on a monthly basis, it did not establish any similar monthly use for best price or customary prompt pay discounts. For these reasons, we propose to interpret section 6001(b) of the DRA to require that manufacturers report only AMP to CMS on a monthly basis beginning January 1, 2007. To implement this provision, we would require in § 447.510(d) that manufacturers must submit monthly AMP to CMS not later than 30 days after each month. We would also require manufacturers to report quarterly AMP, best price, and customary prompt pay discounts on a quarterly basis.

We propose that the monthly AMP will be calculated the same as the quarterly AMP, with the following exceptions. The time frame represented by the monthly AMP would be one calendar month instead of a calendar

quarter and once reported, would not be subject to revision later than 30 days after each month. Because we recognize that industry pricing practices sometimes result in rebates or other price concessions being given by manufacturers to purchasers at the end of a calendar quarter, if the monthly AMP were calculated simply using sales in that month, these pricing practices might result in fluctuations between the AMP for the first two months and the AMP for the third month in a calendar quarter. In order to maximize the usefulness of the monthly AMP and minimize volatility in the prices, we propose allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these rebates or other price concessions in the monthly AMPs reported to CMS throughout the quarter. We considered applying this same methodology to other cumulative rebates or other price concessions over longer periods of time, but are not certain that such rebates or other price concessions could be allocated with respect to monthly AMP calculations. We invite comments on allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. We also considered allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (i.e., a rolling three-month AMP). While this methodology may minimize volatility in the data, we believe it would be fairly complex for manufacturers to operationalize. We encourage comments on the appropriate methodology for calculating monthly AMP.

Section 6001(b)(2)(C) of the DRA amended the confidentiality requirements at section 1927(b)(3)(D) of the Act by adding an exception for AMP disclosure through a Web site accessible to the public. The statute does not specify that this exception only applies to monthly AMP; therefore, we also propose to make the quarterly AMP publicly available. We note that the quarterly AMP would not necessarily be identical to the monthly AMP due to the potential differences in AMP from one timeframe to the next.

Section 6001(d)(1) of the DRA modified section 1927(b)(3)(A)(iii) of the Act by adding a requirement that manufacturers report nominal prices for calendar quarters beginning on or after January 1, 2007 to the Secretary. To implement this provision, we propose to require that manufacturers report nominal price exception data to CMS on a quarterly basis. We further propose that nominal price exception data shall

be reported as an aggregate dollar amount which includes all nominal price sales to the entities listed in § 447.508(a) of this subpart for the rebate period.

Section 1927(b)(3)(C) of the Act describes penalties for manufacturers that provide false information or fail to provide timely information to CMS. In light of these requirements, we propose to require that manufacturers certify the pricing reports they submit to CMS in accordance with § 447.510. We propose to adopt the certification requirements established by the Medicare Part B Program for ASP in the interim final rule with comment period published on April 6, 2004. Each manufacturer's pricing reports would be certified by the manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

We propose that all product and pricing data, whether submitted on a quarterly or monthly basis, be submitted to CMS in an electronic format. When the Medicaid Drug Rebate Program was first implemented in 1991, electronic data transfer was one of three data submission options as the use of such electronic media was not yet as commonplace as it is today. Due to the new monthly data reporting requirements and additional quarterly data reporting requirements, we propose to require manufacturers to use one uniform data transmission format to transmit and collect these data. CMS will issue operational instructions to provide additional guidance regarding the new electronic data submission requirements.

Aggregate Upper Limits of Payment—Section 447.512

We propose that the existing § 447.331 be revised and redesignated as a new § 447.512. We propose to revise subsection (a) to clarify that the upper limit for multiple source drugs applies in the aggregate. We also propose to update several cross-references to provisions in subpart I.

Upper Limits for Multiple Source Drugs—Section 447.514

We propose that the existing § 447.332 be revised in a new § 447.514.

A. Upper Limits for Multiple Source Drugs

Existing regulations at 42 CFR 447.331, 447.332 and 447.334 address upper limits for payment of drugs covered under the Medicaid program. We propose to redesignate existing

regulations at §§ 447.331, 447.332, and 447.334 as new regulations at §§ 447.512, 447.514, and 447.516, respectively.

Existing regulations at § 447.332(a)(1)(i) state that an upper limit for a multiple source drug may be established if all of the formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent in the current edition of the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations."

Section 1927(e)(4) of the Act, as amended by OBRA 90, expanded the criteria for multiple source drugs subject to FUL reimbursement. Specifically, the statute required CMS to establish an upper payment limit for each multiple source drug when there are at least three therapeutically and pharmaceutically equivalent multiple source drugs, regardless of whether all additional formulations are rated as such. Effective January 1, 2007, the DRA changed the requirement such that a FUL must be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent.

Currently, if all formulations of a multiple source drug are identified as A-rated in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," at least two formulations must be listed in that publication for CMS to establish a FUL for that drug. If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" for CMS to establish a FUL for the drug. If a product meets the FDA criteria described above, we confirm that at least three suppliers (i.e., manufacturers, wholesalers, repackagers, re-labelers or any other entity from which a drug can be purchased) list the drug in published compendia of cost information for drugs available for sale nationally (e.g., Red Book, First DataBank, or Medi-Span). Then, using these pricing compendia, we select the lowest price (e.g., the average wholesale price, wholesale acquisition cost, or direct price) from among the A-rated formulations of a particular drug and apply the formula described in existing § 447.332 to determine the FUL for that drug. FUL lists and changes to those lists based on the methodology set forth in the statute and regulations are issued periodically through Medicaid program issuances and are posted on the CMS Web site.

By the term, “therapeutically equivalent,” we mean drugs that are identified as A-rated in the current edition of the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (including supplements or successor publications). We propose that the FUL will be established, as per section 1927(e)(4) of the Act, only using an “A” rated drug. However, we propose to continue our current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent, (e.g., B-rated drugs). We believe it is appropriate to apply the FUL to B-rated drugs in order not to encourage pharmacies to substitute B-rated drugs to avoid the FUL in the case where B-rated drugs would be excluded from the FUL. Current regulation does not prohibit or exclude B-rated drugs from the FUL reimbursement.

We propose revising the methodology we use to establish FULs for multiple source drugs based on the modifications made by the DRA. Specifically, sections 6001(a)(3) and (4) of the DRA changed the definition of multiple source drug established in section 1927(k)(7)(A)(i) of the Act to mean, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”). Also, section 6001(a)(1) of the DRA changed the requirement for a FUL to be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent to a requirement for a FUL when the FDA has established such a rating for two or more products. Therefore, we propose in § 447.514(a)(1)(ii) that a FUL will be set when at least two suppliers (e.g., manufacturers, wholesalers, repackagers, or re-labelers) list the drug in a nationally available pricing compendia (e.g., Red Book, First DataBank, or Medi-Span).

Existing regulations at § 447.332(b) specify that the agency’s payments for multiple source drugs identified and listed must not exceed, in the aggregate, payment levels determined by applying, for each drug entity, a reasonable dispensing fee established by the agency, plus an amount that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national pricing compendia) that can be purchased by pharmacies in quantities of 100 tablets

or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

Section 6001(a)(2) of the DRA added section 1927(e)(5) to the Act that changed the formula used to establish the FUL for multiple source drugs. Effective January 1, 2007, the upper limit for multiple source drugs shall be established at 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent. The currently reported AMP is based on the nine-digit NDC and is specific only to the product code, combining all package sizes of the drug into the same computation of AMP. We propose to continue to use the AMP calculated at the nine-digit NDC for the FUL calculation. In accordance with the DRA amendments, we will no longer take the individual 11-digit NDC, and thereby the most commonly used package size into consideration when computing the FUL because the currently reported AMP does not differentiate among package sizes.

We considered using the 11-digit NDC to calculate the AMP, which would require manufacturers to report the AMP at the 11-digit NDC for each package size and that doing so would offer other advantages to the program for FULs and other purposes. An AMP at the 11-digit NDC would allow us to compute a FUL based on the most common package size as specified in current regulations. We do not believe computing an AMP at the 11-digit NDC would be significantly more difficult than computing the AMP at the nine-digit NDC as the data from each of the 11-digit NDCs is combined into the current AMP. The AMP at the 11-digit NDC would also align with State Medicaid drug payments that are based on the package size. It would also allow us to more closely examine manufacturer price calculations and allow the States and the public to know the AMP for the drug for each package size. It would also allow 340B covered entities, which are entitled to buy drugs at a discount that is in part based on calculations related to AMP, to know what the pricing is for each package size, as 340B ceiling prices are established per package size. Calculating the AMP at the 11-digit NDC level permits greater transparency, and may increase accuracy and reduce errors for the 340B covered entities where prices are established for a package-size product rather than a per unit cost using the product’s weighted average AMP.

However, the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that the Congress intended that AMP should be restructured to collect it by 11-digit NDCs. We are proposing to use the currently reported 9-digit AMP for calculating the FUL. Changing the current method of calculating the AMP would require manufacturers to make significant changes to their reporting systems and have an unknown effect on the calculation of rebates in the existing Medicaid Drug Rebate Program. In State Medicaid payment systems that consider a number of different factors in deriving payment rates, we also believe it would offer minimal advantages. Furthermore, we expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size.

We specifically ask for comments on the alternative approach of using the 11-digit NDC to calculate the AMP. We will consider comments on the merits of using both approaches in calculating the AMP for the FUL.

In computing the FUL, we propose that the monthly AMP submitted by the manufacturer will be used. Using the monthly AMP will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act, wherein the Secretary, after receiving notification that a therapeutically equivalent drug product is generally available, shall determine within 7 days if that drug product should have a FUL.

Section 6001(c)(1) of the DRA redefines AMP to exclude customary prompt pay discounts extended to wholesalers. Due to this change in the computation, and the requirement that monthly AMP first be reported as of January 1, 2007, we propose that a FUL update of drugs, using the new methodology first be published when the revised AMPs are available and processed.

We propose to adopt additional criteria to ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations. When establishing a FUL, we propose to disregard the AMP of an NDC which has been terminated. The AMP of a terminated NDC will not be used to set

the FUL beginning with the first day of the month after the actual termination date reported by the manufacturer. This refinement may not capture all outlier AMPs that would offset the availability of drugs at the FUL price. It is possible that a product that is not discontinued may be available on a limited basis at a very low price. As a further safeguard to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs, we propose to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. That is to say, that the AMP of the lowest priced therapeutically equivalent drug will be used to establish the FUL, except in cases where this AMP is more than 70 percent below the second lowest AMP. In those cases, the second lowest AMP will be used in the FUL calculation. We propose to use this percentage calculation as a benchmark to prevent an outlier price from determining the FUL, but invite comments as to whether this percentage is an appropriate measure to use. We did consider other options, such as 60 percent below the next highest AMP so that at least drugs of two different manufacturers would be in the FULs group, but we were concerned that this percentage was insufficient to encourage competition where the cost of a particular drug was dropping rapidly. We also considered a test of a drug priced 90 percent below the next lowest priced drug, in line with how we look on nominal prices, as an indicator that the manufacturer was offering this drug on a not-for-profit basis. However, we note that nominal price relates to best price for some sales and it is unlikely a manufacturer would sell all of its drugs at this price. We welcome suggestions about other means to address outliers and whether outliers should be addressed at all.

We are proposing an exception to the 30 percent carve-out policy when the FUL group only includes the innovator single source drug and the first new generic in the market, including an authorized generic. In this event, we would not apply the 30-percent rule as we believe the DRA intends that a FUL be set when new generic drugs become generally available so as to encourage greater utilization of a generic drug when the price is set less than its brand name counterpart.

We invite comments from the public on all issues set forth in this subpart. We invite suggestions on how best to accomplish the goal of ensuring that the

use of AMP in calculating the FUL will ensure that a drug is available nationally at the FUL price. Please submit data supporting your proposal when available.

Upper Limits for Drugs Furnished as Part of Services—Section 447.516

We propose that the existing § 447.334 be redesignated as a new § 447.516.

State Plan Requirements, Findings and Assurances—Section 447.518

We propose that the existing § 447.333 be redesignated as a new § 447.518.

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.520

Prior to the DRA, many States did not collect rebates on physician-administered drugs when they were not identified by NDC number because the NDC number is necessary for States to bill manufacturers for rebates. In its report, "Medicaid Rebates for Physician Administered Drugs" (April 2004, OEI-03-02-00660), the OIG reported that, by 2003, 24 States either required providers to bill using NDC numbers or identified NDC numbers using a Healthcare Common Procedure Coding System (HCPCS)-to-NDC crosswalk for physician-administered drugs in order to collect rebates. Four of the 24 States were able to collect rebates for all physician-administered drugs, both single source and multiple source drugs (one State only collected these rebates from targeted providers). Section 6002 of the DRA added sections 1927(a)(7) and 1903(i)(10)(C) to the Act to require that States collect rebates on certain physician-administered drugs in order for FFP to be available for these drugs.

Section 1927(a)(7)(A) of the Act requires that, effective January 1, 2006, in order for FFP to be available, States must require the submission of utilization data for single source physician-administered drugs using HCPCS codes or NDC numbers. (HCPCS codes are numeric and alpha-numeric codes assigned by CMS to every medical or surgical supply, service, orthotic, prosthetic and generic or brand name drug for the purpose of reporting healthcare transactions for claims billing. Physician-administered drugs are assigned alpha-numeric HCPCS codes, and are commonly referred to as J-codes. However, physician-administered drugs are also coded using other letters of the alphabet. For this reason, we will refer to the coding system, HCPCS, as opposed to one set of alpha-numeric codes in our discussion of section 6002

requirements.) If States collect HCPCS codes for single source drugs, they can crosswalk these codes to NDC numbers because most HCPCS codes for single source drugs include only one NDC in order to collect rebates.

Section 1927(a)(7)(C) of the Act requires that, beginning January 1, 2007, States must provide for the submission of claims data with respect to physician-administered drugs (both single source and multiple source drugs) using NDC numbers, unless the Secretary specifies that an alternative coding system can be used. The Secretary does not plan to specify an alternative coding system because we believe that NDC numbers are well established in the medical community and provide States the most useful information to collect rebates.

Section 1927(a)(7)(B) of the Act requires the Secretary, by January 1, 2007, to publish a list of the 20 multiple source physician-administered drugs with the highest dollar volume dispensed under the Medicaid program. We propose that the list will be developed by the Secretary using data from the Medicaid Statistical Information System and published on the CMS Web site.

Section 1927(a)(7)(B)(ii) of the Act (when read with other DRA amendments) requires that, effective January 1, 2008, in order for FFP to be available, States must provide for the submission of claims for physician-administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

We propose, for the purpose of this section, that the term "physician-administered drugs" be defined as covered outpatient drugs under section 1927(k)(2) of the Act (many are also covered by Medicare Part B) that are typically furnished incident to a physician's service. These drugs are usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting. Examples include injectables: Lupron acetate for depot suspension (primarily used to treat prostate cancer), epoetin alpha (injectable drug primarily used to treat cancer), anti-emetic drugs (injectable drug primarily used to treat nausea resulting from chemotherapy), intravenous drugs primarily used to treat cancer (paclitaxel and docetaxel), infliximab primarily used to treat rheumatoid arthritis, and rituximab primarily used to treat non-Hodgkin's lymphoma. We believe that some oral self-administered drugs (administered in an outpatient clinical setting), such as oral anti-cancer drugs, oral anti-emetic

drugs should also be included in the designation of physician-administered drugs consistent with Part B policy and sections 1861(s)(2)(Q) and (T) of the Act.

Section 1927(a)(7)(D) of the Act allows the Secretary to grant States extensions if they need additional time to implement or modify reporting systems to comply with this section. We are not proposing any criteria for reviewing these extension requests as we expect that most, if not all States will be able to meet the statutory deadlines for collection of NDC numbers on claims. Most States are already collecting rebates for single source drugs that are provided in a physician's office. For multiple source drugs, the States have nearly two years following enactment of the DRA before FFP would be denied for the 20 multiple source drugs specified by the Secretary as having the highest dollar volume.

We expect that States will require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States. This will also advantage States because rebates will be collectible on all physician-administered drugs.

For States not currently billing manufacturers for rebates on single source drugs, we believe that the Medicare Part B crosswalk may be helpful to crosswalk HCPCS codes to NDC numbers. This crosswalk may be found on the CMS Web site at <http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02.asp?files.asp>.

To implement the provisions set forth in section 6002, we propose a new § 447.520. In § 447.520(a), we would require States to require that claims for physician-administered drugs be submitted using codes that identify the drugs sufficiently to bill a manufacturer for rebates in order for the State to receive FFP. In § 447.520(b), we would require States to require providers to submit claims using NDC numbers. In § 447.520(c), we would allow States that require additional time to comply with the requirements of this section to apply to the Secretary for an extension.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information

collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Requirements for Manufacturers (§ 447.510)

Proposed § 447.510 states that a manufacturer must report, electronically, product and pricing information to CMS not later than 30 days after the end of the rebate period. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. Detailed information pertaining to the manufacturer's reporting requirements is located under §§ 447.510(a), (b), (c), (d), and (e).

The burden associated with these new requirements is the time and effort it would take for a drug manufacturer to gather product and pricing information and submit it to CMS in an electronic format. We estimate that these requirements would affect the approximately 550 drug manufacturers that currently participate in the Medicaid Drug Rebate Program. Our current reporting and recordkeeping hour burden for each manufacturer in the Medicaid Drug Rebate Program is 71 hours per quarter or 284 hours annually. We believe the new reporting requirements will require less than half of this time. Specifically, we believe it would take each manufacturer 31 hours per quarter or 124 hours annually to report additional new information to CMS. The total estimated burden on all drug manufacturers associated with the new requirements under § 447.510 is 68,200 annual hours.

Section 447.510(f) requires a manufacturer to retain records for ten years from the date the manufacturer reports data to CMS for that rebate period. The ten-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS. As stated under § 447.510(f)(2), there are certain instances when records must be maintained beyond the ten-year period.

While this requirement is subject to the PRA, the retention of quarterly data it is not a new requirement. While this requirement will now also apply to monthly AMP data, we believe a similar set of data is now retained to support the quarterly retention requirement. Therefore, we believe this regulation imposes no additional burden on the drug manufacturer.

FFP: Conditions Relating to Physician-Administered Drugs. (§ 447.520)

Section 447.520 requires providers, effective January 1, 2007, to submit claims to the State for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

Assuming all States impose this requirement, the burden associated with this requirement is the time and effort it would take for a physician's office, hospital outpatient department or other entity (e.g., non profit facilities) to include the NDC on claims submitted to the State. We estimate this requirement would affect an excess of 20,000 physicians, hospitals with outpatient departments and other entities that would submit approximately 3,910,000 claims annually. We believe this would take approximately 15 seconds per claim. We estimated the cost based on the average annual wage and benefits paid for office and administrative support services in 2006 of \$21.14 per hour (<http://www.bls.gov/news.release/pdf/ecec.pdf>). The per claim cost would be under 9 cents.

Section 447.520(c) allows States requiring additional time to comply with the requirements of this section to apply for an extension. The burden associated with this requirement is the time and effort it would take for each State to apply for a one-time extension. We estimate that it would take five hours for each State to apply for the extension; however, we believe that no State will apply. Therefore, we believe this requirement to be exempt as specified at 5 CFR 1320.3(c)(4).

We have submitted a copy of this proposed rule to the OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by the OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn: Melissa Musotto, [CMS-2238-P], Room C4-26-05, 7500 Security Boulevard, Baltimore, MD

21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Katherine Astrich, CMS Desk Officer, CMS–2238–P, katherine_astrich@omb.eop.gov. Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” February 20, 2007, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption “Impact Analysis” at the beginning of your comments].

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132, and the Congressional Review Act (CRA, 5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with “economically significant” effects (\$100 million or more in any 1 year). We believe this rule will have an economically significant effect. We believe the rule would save \$8.4 billion over the next five years (\$4.93 billion Federal savings and \$3.52 billion State savings as shown in the table below). This figure represents a 5.6 percent reduction in total Medicaid drug expenditures in Federal fiscal years 2007–2011. We consider this proposed rule to be a major rule for purposes of the CRA.

STATE AND FEDERAL SAVINGS OVER 5 YEARS

[In millions]

DRA section and provision	FFY Federal State	2007	2008	2009	2010	2011	2007–11 Total savings
Section 6001—Federal Upper Payment Limits and Other Provisions.	Federal	\$465	\$750	\$1,075	\$1,155	\$1,250	\$4,695
	State	330	535	765	825	890	3,345
	Total	795	1,285	1,840	1,980	2,140	8,040
Section 6002—Rebates on Physician-Administered Drugs.	Federal	18	19	20	22	24	103
	State	13	14	15	16	18	76
	Total	31	33	35	38	42	179
Section 6003—Authorized Generics in Rebate Best Price.	Federal	10	25	28	32	36	131
	State	7	19	21	24	27	98
	Total	17	44	49	56	63	229
Total Savings for FFY	Federal	493	794	1,123	1209	1310	4,929
	State	350	568	801	865	935	3,519
	Total	843	1,362	1,924	2074	2245	8,448

All savings estimates were developed by the Office of the Actuary in CMS. We note that the Congressional Budget Office, in its estimates of the budgetary effects of these provisions of the DRA, reached an almost identical estimate for these years, about \$4.8 billion in Federal outlay reduction compared to the CMS estimate of \$4.9 billion.

Savings estimates for section 6001 of the DRA—FULs and other provisions—were derived from simulations of the new FULs performed using price and utilization data from the Medicaid Drug Rebate Program combined with generic group codes from First DataBank. Percent savings from these simulations

were applied to projected Medicaid prescription drug spending developed for the President’s fiscal year 2007 budget. Savings were phased in over three years to allow for implementation lags. On the previous chart, the estimate for FFY 2007 through FFY 2010 includes \$5 million for the retail price survey.

The savings estimates for section 6002 of the DRA—rebates on physician-administered drugs—are based on the 2004 OIG report, “Medicaid Rebates for Physician-Administered Drugs.” A key finding of the report is the amount of additional rebates that could have been collected in 2001 if all States had

collected rebates on physician-administered drugs. This amount was then projected forward using historical data (2001–2005) and projections consistent with the 2007 President’s Budget forecast for Medicaid spending to develop the total estimated impact.

The savings estimates for section 6003 of the DRA—Reporting of authorized generics for Medicaid rebates—are based on the consensus of Medicaid experts and the review of available and relevant data. After estimating the impact of the proposal in the first year of implementation, the total impact was projected using assumptions consistent with the 2007 President’s Budget

forecast for Medicaid spending as well as adjustments given that the proposal is limited to a subset of the prescription drug market.

None of the estimates include Federal or State administrative costs. We believe these costs would be small as they involve changes in work processes rather than new activities. The resulting program savings would be many times these costs.

The RFA requires agencies to analyze options for regulatory relief of small businesses and other small entities if a proposed or final rule would have a "significant impact on a substantive number of small entities." For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, three types of small business entities are potentially affected by this regulation. They are small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician-administered drugs. We will discuss each type of business in turn.

According to the Small Business Administration's (SBA) size standards, drug manufacturers are small businesses if they have fewer than 500 employees (<http://www.sba.gov/size/sizetable2002.html>). Approximately 550 drug manufacturers participate in the Medicaid Drug Rebate Program. We believe that most of these manufacturers are small businesses. We anticipate that this rule would have a small impact on small drug manufacturers. The rule would require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers would be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. We believe that drug manufacturers currently have these data; therefore, the new requirement does not require new data collection. Rather, it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal. In addition, the proposed regulation would affect the level of rebates due from manufacturers. The DRA provides that customary prompt

pay discounts be excluded from AMP. This would result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about 2 percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts would cost manufacturers up to \$160 million (2 percent of \$8 billion in rebate payments annually). In this proposed regulation we also would remove sales to nursing home pharmacies from AMP. We have been told by industry representatives that nursing home pharmacies receive larger discounts than other sectors, thus resulting in an increase in AMP from this change. However, because we have no independent data on the cost of drugs to nursing home pharmacies, we cannot quantify the effect of this provision other than to say that we believe it would increase rebates owed by drug manufacturers.

According to the SBA's size standards, a retail pharmacy is a small business if it has revenues of \$ 6.5 million or less in 1 year (<http://www.sba.gov/size/sizetable2002.html>). The SBA estimates that there are about 18,000 small pharmacies. These pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs would provide States two new data points to use to set payment rates. Beginning in January 2007, States may use AMP and retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list. As analyzed in detail below, we believe that these legislatively mandated section 6001 savings will potentially have a "significant impact" on some small, independent pharmacies. The analysis in this section, together with the remainder of the preamble, constitutes an Initial Regulatory Flexibility Analysis (IRFA) for purposes of compliance with the RFA.

According to the SBA's size standards, physician practices are small

businesses if they have revenues of \$9 million or less in 1 year (<http://www.sba.gov/size/sizetable2002.html>). Nearly all of the approximately 20,000 physician's practices that specialize in oncology, rheumatology and urology may experience some administrative burden due to new requirements that claims include the NDC for drugs administered by these physicians. These practices would be required to transfer the NDC code for drugs administered by a physician to the electronic or paper claim. We estimate that 3,910,000 claims would be submitted a year. We derived this number by multiplying the 23 million annual Part B claims by the percentage (17) of Medicare beneficiaries who are also Medicaid beneficiaries. We believe most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare. We then assume that it would take 15 seconds per claim. Multiplying 3,910,000 by 15 seconds equals 58,650,000 seconds or 16,292 hours (58,650,000/3600 seconds per hour). We multiplied 16,292 hours by the hourly wage and benefit rate of \$21.14 for office and administrative staff published by the Department of Labor, Bureau of Labor Statistics for March 2006 to estimate the annual cost to be \$344,000. We divided the total cost of \$344,000 by the 3,910,000 claims to estimate the cost per claim would be under 9 cents. Calculated another way, the annual cost per physician practice would be under \$20 (\$344,000 divided by 20,000 equals about \$17). Accordingly, we believe that there is no "significant impact" on these physicians.

According to the SBA's size standards, hospitals are small businesses if they have yearly revenue of \$31.5 million or less (<http://www.sba.gov/size/sizetable2002.html>). As with physician practices, outpatient units of hospitals would need to include NDCs on claims for physician-administered drugs. Outpatient hospital claims for physician-administered drugs are included in the 3,910,000 annual total claims discussed in the previous paragraph. However, we believe that these costs could be reduced or eliminated with a one-time systems change to capture this code in the billing system. In any case, the total cost of this change to hospitals would be small, and we believe that there is no "significant impact" on hospitals.

Other small entities such as non-profit providers may also be affected by this provision. We do not have data to quantify how many of the 3,910,000 annual total claims are submitted by

these entities. In any case, the cost would be under 9 cents per claim.

Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not know how many of these hospitals have outpatient departments. However, we believe that this rule would not have a significant impact on small rural hospitals because the only provision that would affect small rural hospitals is the requirement for those hospitals to include the NDC on bills for drugs administered by physicians in the outpatient department. As the national annual cost of this provision is estimated at \$344,000, the impact on small rural hospitals would be minimal.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on States and private entities require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$125 million. This proposed rule would mandate that drug manufacturers provide information on drug prices, and that these data be used in calculating FULs. However, our estimate of costs to manufacturers (see next section) falls far below the threshold and we anticipate this rule would save States \$3.5 billion over the 5-year period from October 1, 2006 through September 30, 2011.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this proposed rule would impose only minimal new administrative burden on States and yield substantial savings to States, we believe that these costs can be absorbed by States from the substantial savings they would accrue.

B. Anticipated Effects

1. Effects on Drug Manufacturers

As previously indicated, approximately 550 drug manufacturers participate in the Medicaid Drug Rebate

program. The rule would require all drug manufacturers participating in the Medicaid Drug Rebate Program to submit pricing information (AMP) on each of their drug products on a monthly basis. Currently drug manufacturers are required to submit similar information quarterly. In addition, drug manufacturers would be required to submit two additional pricing data elements—customary prompt pay discounts and nominal prices—on each of their drugs on a quarterly basis. We believe that drug manufacturers currently have these data; therefore, the new requirement would not require new data collection. Rather it simply requires that existing information be reported to CMS. For this reason, we believe the burden to be minimal. The estimated startup burden to the manufacturers is \$27.5 million for a one-time systems upgrade, or \$50,000 for each of the 550 manufacturers that participate in the Medicaid Drug Rebate Program. To estimate the ongoing burden, we expect that the manufacturers would each spend 208 hours annually (114,400 total hours annually) in complying with these requirements. The estimated annual operational expenses are \$5.7 million, which is 114,400 total annual hours multiplied by \$37.50 per labor hour in wages and benefits, or \$4.3 million in labor burden, plus \$1.4 million in technical support.

In addition, the proposed regulation would affect the level of rebates due from manufacturers. The DRA provides that customary prompt pay discounts be excluded from AMP. This would result in higher AMPs and, consequently, higher rebate payments. We have been told informally by manufacturers that customary prompt pay discounts are generally about two percent. We have found no independent source to confirm this percentage. We also do not know what percent of sales qualify for customary prompt pay discounts. Based on this limited information, we believe that the removal of customary prompt pay discounts would cost manufacturers up to \$160 million (2 percent of \$8 billion in rebate payments annually). In this proposed regulation, we also would remove sales to nursing home pharmacies from AMP. We have been told by industry representatives that nursing home pharmacies receive larger discounts than other sectors, thus resulting in an increase in AMP. However, because we have no independent data on the cost of drugs to nursing home pharmacies, we cannot quantify the effect of this provision other than to say that we believe it

would increase rebates owed by drug manufacturers.

2. Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the table above, we estimate five-year State savings of over \$3.5 billion. State administrative costs associated with this regulation are minor as States currently pay based on a FUL for drugs subject to that limit, determine their drug reimbursement rates, and collect claims information on physician-administered drugs.

3. Effects on Retail Pharmacies

Retail pharmacies would be affected by this regulation, as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid payment for drugs subject to the limits. The savings for section 6001 of the DRA reflect this statutory change. The other provisions concerning payment for drugs would provide States two new data points to use to set payment rates. Beginning in January 2007, States may use AMP and retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list that may result if States change their payment methodologies.

The savings to the Medicaid program would largely be realized through lower payments to pharmacies. As shown earlier in this analysis, the annual effect of lower FULs and related changes will likely reduce pharmacy revenues by about \$800 million in 2007, increasing to a \$2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data summarized by the National Association of Chain Drug Stores (<http://www.nacds.org/wmspage.cfm?parm1=507>), total retail prescription sales in the United States, including chain drug stores, independent drug stores, supermarket, and mail order, totaled about \$230 billion in 2005. Assuming, conservatively, that sales will rise at only five percent a year, 2007 sales would be over \$250 billion and 2011 sales well over \$300 billion. Thus, the effect of this proposed rule would be to reduce retail prescription drug revenues by less than one percent, on average. Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as

prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs.

Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions. Because of these uncertainties, we have concluded that this proposed rule is likely to have a "significant impact" on some pharmacies.

4. Effects on Physicians

This regulation would affect physician practices that provide and bill Medicaid for physician-administered drugs. This includes about 20,000 physicians as well as hospitals with outpatient departments. The effect on physicians is the same as discussed in section A—Overall Impact above for small businesses because all or nearly all physician offices are small businesses.

5. Effects on Hospitals

This regulation would affect hospitals with outpatient departments that provide and bill Medicaid for physician-administered drugs. As discussed above, hospitals with outpatient departments would need to include the NDC on claims for physician-administered drugs. We believe this would need to be done manually or would require a one-time systems change. We believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change.

We also note that CMS has encouraged States to collect information on physician-administered drug claims to enable them to collect rebates. Some States have required that NDCs be included on claims and others are in the process of doing so. We expect that, in the absence of the DRA requirement, the number of States requiring NDCs on these claims would have increased.

6. Effects on Small Business Entities

As previously discussed, for purposes of the RFA, three types of small business entities are potentially affected by this regulation. This regulation would affect small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, small retail pharmacies, and physicians and other practitioners (including small hospitals or other entities such as non-profit providers).

According to the SBA's size standards, we believe that most of the 550 pharmaceutical manufacturers in the Medicaid Drug Rebate Program are small businesses. We previously indicated that this rule impacts drug manufacturers by requiring them to submit pricing information (AMP) on each of their drug products on a monthly basis with an estimated impact that is minimal. The rule would also increase the amount of drug rebates that manufacturers would pay as a result of removing customary prompt pay discounts and nursing home sales from AMP, which is used in the rebate calculation. The exclusion of customary prompt pay discounts would cost manufacturers up to \$160 million (2 percent of \$8 billion in rebate payments annually). Additional detail regarding the effects of this proposed rule for the determination of drug prices and calculation of drug rebate liability for drug manufacturers is described in the preamble under "Definition of Retail Pharmacy Class of Trade and Determination of AMP."

We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to specifically estimate quantitative effects

on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions. The preamble under "Definition of Retail Pharmacy Class of Trade and Determination of AMP" provides additional information regarding the entities included in the retail pharmacy class of trade and the discounts or other price concessions for drugs provided to the retail pharmacy class of trade. As shown earlier, the annual effect of lower FULs and related changes will likely reduce overall pharmacy revenues by about \$800 million in 2007, increasing to a \$2 billion reduction annually by 2011.

Nearly all of the approximately 20,000 physician practices that specialize in oncology, rheumatology and urology are considered small businesses. The rule would impose some administrative burden on these practices due to new requirements that claims include the NDC for physician-administered drugs. As shown earlier, we believe that the annual cost per claim would be under 9 cents and the annual cost per physician practice would be under \$20. Accordingly, we believe that there is no significant impact on these physician practices.

We also previously indicated that this rule would not have a significant impact on the operations of small rural hospitals. There are approximately 700 small rural hospitals that meet the small business standard. As previously discussed, small rural hospitals would need to include the NDC on claims for physician-administered drugs through outpatient departments. We do not have data to quantify how many of the overall claims for physician-administered drugs are submitted by these 700 small rural hospitals. In any case, the cost would be under 9 cents per claim.

The following chart depicts the number of small entities and the estimated economic impact for each category of small entity affected by this rule.

Small entity	Number affected by rule	Estimated economic impact
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program.	550	\$160 million (2 percent of \$8 billion) higher rebates result from removal of customary prompt pay discounts from rebate calculations. Independent cost data not available for excluded nursing home drug sales that are expected to increase rebate cost.
Small Retail Pharmacies	18,000	Reduces overall pharmacy revenues by about \$800 million in 2007 increasing to \$2 billion annually by 2011. Unable to quantitatively estimate effects on small retail pharmacies, particularly in low income areas.

Small entity	Number affected by rule	Estimated economic impact
Physicians in their Offices, Hospital Outpatient Settings or Other Entities (e.g., Non-profit Facilities) that Specialize in Oncology, Rheumatology and Urology.	20,000	Under 9 cents per claim to enter NDC number. About \$17 annual cost per physician practice to enter NDC number on claims for physician-administered drugs. Total estimated impact is \$344,000.
Small Rural Hospitals	700	Minimal impact.

C. Alternatives Considered

We considered a number of different policies and approaches during the development of the proposed rule.

With regard to the definition of AMP, we considered one definition for quarterly AMP and a different definition for monthly AMP. However, we believe the better reading of statute is for AMP to be defined the same way for quarterly or monthly reporting.

We also considered redefining the entities included in "retail pharmacy class of trade" for purposes of the definition of AMP. Options considered included whether to include or exclude sales to nursing home pharmacies, PBMs, and mail order pharmacies. We chose to propose to exclude sales to nursing home pharmacies.

We considered retaining the current base date AMP rather than allowing manufacturers to recalculate their base date AMP to reflect the revised definition of AMP. However, we decided that retaining the current base date AMP is unwarranted because it would create a financial burden on manufacturers that was not intended by section 6001 of the DRA.

We considered several options concerning the timeframe to be covered by the monthly AMP. We considered requiring manufacturers to report the same quarterly AMP three times over the quarter, and reflect any changes to the quarterly AMP vis-à-vis the monthly reports. However, we did not believe that this timeframe would provide useful pricing information to States. We also considered establishing a rolling three-month period for the monthly AMP. While this may yield updated pricing information, we felt this would be too burdensome for manufacturers to implement.

We considered proposing to extend the nominal price exclusion from best

price to other facilities or entities that the Secretary determines to be safety net providers to which sales of drugs at nominal prices would be appropriate. However, we were concerned that expanding the list of entities eligible for nominal pricing would drive up best price, which would effectively lower the amount of rebates manufacturers pay for Medicaid drugs.

We considered using a non-weighted AMP, which is specific to a package size, to establish the FUL. However, we decided to continue to base AMP on all package sizes for each drug. We did not find any indication that the Congress intended to change how package size is used for AMP. Such a change would be burdensome on manufacturers and would have no impact on how States pay for drugs.

We considered not making an exception to using the lowest AMP for drugs in a FUL group to establish the upper limit for the group. However, we were concerned that low outlier prices might result in only one drug being available at or near the FUL price and that a sufficient supply of the drug to meet the national Medicaid need may not be available at that price.

As discussed extensively earlier in the preamble, we believe that mail order sales and the activities of PBMs are an important part of the wholesale and retail markets for drugs. They reflect the realities of today's marketplace for consumers of prescription drugs. However, there are difficulties in dealing with both segments of the market and we specifically request comments on ways to handle these components of the marketplace. We also welcome comments on any options that would maintain the overall savings of the proposed rule, appropriately encompass the entire retail marketplace,

and reduce burden on small pharmacies.

D. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA and four categories of burden-reducing alternatives. We know of no relevant Federal rules that duplicate, overlap, or conflict with the proposed rule. The preceding analysis, together with the rest of this preamble, addresses all these general requirements.

We have not, however, addressed the various categories of burden reduction listed in the RFA as appropriate for IRFAs. These alternatives, such as an exemption from coverage for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not appear to apply in a situation where uniform payment standards are being established. However, we welcome comments with suggestions for improvements we can make, consistent with the statute, to minimize any unnecessary burdens on pharmacies or other affected entities.

E. Accounting Statement

As required by OMB's Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the decreases in Medicaid payments under sections 6001 " 6003 of the DRA. All expenditures are classified as transfers to the Federal and State Medicaid programs from retail pharmacies and drug manufacturers.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2007 TO CY 2011
[In millions/year]

Category	Transfers	Discount rate (percent)	From whom to whom?
Federal Annualized Monetized Transfers.	\$957.8	7	Retail Pharmacies and Drug Manufacturers to the Federal Government.

ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2007 TO CY 2011—Continued
[In millions/year]

Category	Transfers	Discount rate (percent)	From whom to whom?
Other Annualized Monetized Transfers.	973.6	3	Retail Pharmacies and Drug Manufacturers to the State Governments.
	683.8	7	
	695.1	3	

F. Conclusion

We estimate savings from this regulation of \$8.4 billion over five years, \$4.9 billion to the Federal Government and \$3.5 billion to the States. Most of these savings result from a change in how the FULs on multiple source drugs are calculated and from a change in how authorized generic drugs are treated for AMP and best price. The majority of the savings would come from lower reimbursement to retail pharmacies. The provision on physician-administered drugs does not change the legal liability of drug manufacturers for paying rebates but would make it easier for States to collect these rebates.

While the effects of this regulation are substantial, they are a result of changes to the law.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the OMB.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart F—Payment Methods for Other Institutional and Non-institutional Services

2. Section 447.300 is revised to read as follows:

§ 447.300 Basis and purpose.

In this subpart, § 447.302 through § 447.325 and § 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of

care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.301 [Removed]

3. Section 447.301 is removed.

§ 447.331 [Removed]

4. Section 447.331 is removed.

§ 447.332 [Removed]

5. Section 447.332 is removed.

§ 447.333 [Removed]

6. Section 447.333 is removed.

§ 447.334 [Removed]

7. Section 447.334 is removed.

8. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.

- 447.500 Basis and purpose.
- 447.502 Definitions.
- 447.504 Determination of AMP.
- 447.505 Determination of best price.
- 447.506 Authorized generic drugs.
- 447.508 Exclusion from best price of certain sales at a nominal price.
- 447.510 Requirements for manufacturers.
- 447.512 Drugs: Aggregate upper limits of payment.
- 447.514 Upper limits for multiple source drugs.
- 447.516 Upper limits for drugs furnished as part of services.
- 447.518 State plan requirements, findings and assurances.
- 447.520 FFP: Conditions relating to physician-administered drugs.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in

expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.

Consumer Price Index—Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the

calendar quarter for which the rebate is paid.

Dispensing fee means the fee which—

(1) Is incurred at the point of sale and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA). It includes a drug product marketed by any cross-licensed producers or distributors operating under the NDA and a covered outpatient drug approved under a product license approval, establishment license approval or antibiotic drug approval.

Manufacturer means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale

distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term "manufacturer" will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term "manufacturer" will also include the entity that does not possess legal title to the NDC.

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.fda.gov/cder/orange/default.htm> or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (*i.e.*, the nine-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the AMP in the same quarter for which the AMP is computed.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a product license approval, establishment license approval, or antibiotic drug approval.

§ 447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and

Cosmetic Act (FFDCA)) for a calendar quarter, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulations) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

(2) Sales to other manufacturers who act as wholesalers and do not

repackage/relabel under the purchaser's NDC, including private labeling agreements;

(3) Sales (direct and indirect) to hospitals, where the drug is used in the outpatient pharmacy;

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in § 440.150 of this chapter, or a State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Discounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade;

(7) Sales directly to patients;

(8) Sales to outpatient clinics;

(9) Sales to mail order pharmacies;

(10) Rebates, discounts, or other price concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade;

(11) Manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail pharmacy class of trade; and

(12) Sales and associated rebates, discounts and other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA-PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).

(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in subsection (a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA);

(3) Any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(4) Sales to hospitals (direct and indirect), where the drug is used in the inpatient setting;

(5) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs);

(6) Sales to long-term care facilities, including nursing home pharmacies;

(7) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;

(8) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;

(9) Manufacturer coupons redeemed by a consumer;

(10) Free goods, not contingent upon any purchase requirement;

(11) Bona fide service fees;

(12) Customary prompt pay discounts extended to wholesalers; and

(13) Returned goods when returned in good faith.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, PBM price concessions, chargebacks, incentives, administrative fees, service fees, (except bona-fide service fees), distribution fees, and any other discounts or price reduction and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

(2) AMP is calculated as a weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during a rebate period. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

§ 447.505 Determination of best price.

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter

for which the AMP is computed. Best price shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provisions of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section and § 447.505 of this subpart, best price for covered outpatient drugs, includes—

(1) Prices to wholesalers;

(2) Prices to any retailer, including PBM rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;

(3) Prices to providers (e.g., hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);

(4) Prices available to non-profit entities;

(5) Prices available to governmental entities within the United States;

(6) Prices of authorized generic drugs;

(7) Prices of sales directly to patients;

(8) Prices available to mail order pharmacies;

(9) Prices available to outpatient clinics;

(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements;

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity; and

(12) Manufacturer coupons redeemed by any entity other than the consumer.

(d) *Prices excluded from best price.*

Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in subsection (a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices paid by an SPAP;

(4) Any depot prices (including Tricare) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-PD plan under Part C of such title with respect to covered Part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates or supplemental rebates paid to Medicaid States agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer's sponsored Drug Discount Card Program;

(8) Manufacturer coupons redeemed by a consumer;

(9) Goods provided free of charge under a manufacturers' patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart; and

(12) Bona fide service fees.

(e) *Further clarification of best price.*

(1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.510 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, authorized generic drug means any drug sold, licensed or marketed under an NDA approved by the FDA under section 505(c) of the FDCA; and marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trade mark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the direct and indirect sales of this drug in its AMP.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA of an authorized generic drug approved under section 505(c) of the FDCA must include the price of such drug in the computation of best price for the single source or innovator multiple source drug during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA,

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38 U.S.C. 8126.

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with § 447.504 of this subpart;

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount which includes discounts paid to all purchasers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Timeframe for reporting revised AMP, best price, customary prompt pay discounts, or nominal prices.* A manufacturer must report to CMS revisions to AMP, best price, customary

prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(c) *Base date AMP report.* (1) A manufacturer must report base date AMP to CMS for the first full calendar quarter following [publication date of the final rule].

(2) Any manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in § 447.504(e) of this subpart.

(d) *Monthly AMP.* (1) Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* In calculating monthly AMP, a manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period. The monthly AMP should be calculated based on the methodology in § 447.504 of this subpart, except the period covered will be one month. Further, monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission.

(3) *Prohibition against reporting revised monthly AMP.* In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's Chief Executive Officer (CEO);

(2) The manufacturer's Chief Financial Officer (CFO); or

(3) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The 10-year time frame applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised quarterly pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.*

(1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in their most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers list the drug, which has met the criteria in paragraph (a)(1)(i) of this section, based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, in establishing the FUL, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 30 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the innovator single source drug and the first new generic or authorized generic drug enters the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the

Secretary as having the highest dollar value under in the Medicaid program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: August 10, 2006.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: October 16, 2006.

Michael O. Leavitt,
Secretary.

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May 12, 2006

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

I am writing regarding Congressional intent relative to Section 6001 of the *Deficit Reduction Act of 2005 (DRA) – Federal Upper Payment Limit for Multiple Source Drugs and Other Payment Provisions*. I expect that this information will be useful guidance as you are preparing to publish the Average Manufacturer Price (AMP) data as required in Section 6001(b)(1) of the DRA.

RELEASE OF INTERIM AMP DATA

As of July 1, 2006 CMS will begin publishing data on the Average Manufacturer Price (AMP). Recommendations regarding AMP are due from the Office of the Inspector General on June 1. The final regulation is due on July 1, 2007. I sought much greater clarification in the definition of AMP because the AMP is currently inconsistently calculated, and, as a result, manufacturers are forced to make numerous assumptions about what to include and not to include that vary greatly by manufacturer.

It is important that your initial publishing of the data makes clear that any data disseminated during 2006 are interim data that are not based on any final regulation. While the AMP data will provide a far more accurate reflection of market prices than anything currently available, I believe that purchasers—both the states in Medicaid and those in the private market—should be cautioned that this AMP data does not reflect final calculations and that significant variation could be possible between the first publication and those published under the final regulation.

DISPENSING FEES

I expect states will very soon begin shifting to a pharmacy payment methodology based on the newly published interim AMP data. CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs. States may have been working under an assumption borne out in numerous reports of the Office of the Inspector General that pharmacies were being reimbursed well beyond the acquisition cost of the drugs and so dispensing fees were set at levels below the actual cost of the dispensing of a drug. States should carefully

consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.

I expect to work with you very closely during the implementation of this very important legislation and look forward to joining your efforts to improve health care for all Americans.

Sincerely yours,

A handwritten signature in dark ink, reading "Chuck Grassley". The signature is written in a cursive, slightly slanted style.

Charles Grassley
Chairman
Senate Committee on Finance

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DETERMINING AVERAGE
MANUFACTURER PRICES FOR
PRESCRIPTION DRUGS UNDER
THE DEFICIT REDUCTION
ACT OF 2005**



Daniel R. Levinson
Inspector General

May 2006
A-06-06-00063

EXECUTIVE SUMMARY

BACKGROUND

Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP to calculate a unit rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States. The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount by the number of units of the drug dispensed to Medicaid beneficiaries.

Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements.

The DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Pursuant to the DRA, CMS must promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

OBJECTIVE

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

SUMMARY OF RESULTS

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work, which has primarily focused on how manufacturers calculate AMP, has found that the manufacturers reviewed interpret AMP requirements differently. Specifically, our findings demonstrate the need to clarify the definition of retail class of trade and the treatment of

pharmacy benefit manager rebates and Medicaid sales in AMP calculations. In addition, work related to the use of AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, they raised additional issues related to the implementation of DRA provisions.

Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

RECOMMENDATIONS

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
 - administrative and service fees,
 - lagged price concessions and returned goods,
 - the frequency of AMP reporting,
 - AMP restatements, and
 - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance. CMS's comments are included as Appendix G.

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INTRODUCTION

BACKGROUND

Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP and, in some cases, best price data to calculate a per unit (e.g., per pill) rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States.¹ The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount for a specific drug by the number of units dispensed to Medicaid beneficiaries.

Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 contains several provisions affecting the Medicaid drug rebate program and Medicaid drug reimbursement. Sections 6001(c) and (g) of the DRA require the calculation of AMP without regard to customary prompt pay discounts effective January 1, 2007. Section 6001(b) requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements. Section 6001(a) of the DRA requires that, effective January 1, 2007, Federal upper limits will be based on 250 percent of AMP for the drug with the lowest AMP rather than 150 percent of the lowest published price for therapeutically equivalent products.

Section 6001(c)(3)(A) of the DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Section 6001(c)(3)(B) requires that CMS promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

¹Section 1927(c)(1)(C) defines best price as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity, excluding certain sales.

Centers for Medicare & Medicaid Services Guidance

Since the Medicaid drug rebate program began in 1991, CMS has issued a regulation (42 CFR § 447.534) addressing only manufacturers' record retention requirements and time limits for submitting AMP recalculations. CMS has also issued guidance to manufacturers in the form of a standardized drug rebate agreement with manufacturers and memorandums called Medicaid drug program releases (releases).

The rebate agreement further defines AMP and provides a definition of wholesalers:

- AMP is defined as “the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number).” The rebate agreement further specifies that cash discounts and all other price reductions that reduce the actual price paid are included in AMP (section I(a) of the rebate agreement).
- A wholesaler is defined as “any entity (including a pharmacy or chain of pharmacies) to which the labeler [manufacturer] sells the Covered Outpatient Drug, but that does not relabel or repack the Covered Outpatient Drug” (section I(ee) of the rebate agreement).

Section I(a) of the rebate agreement also provides that the AMP “for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.” Manufacturers can have payment arrangements with entities that do not take title to or possession of drugs. These arrangements can affect the price realized by the manufacturer without changing the price paid by the purchaser that takes title to or possession of the drugs.

To provide additional clarification on rebate issues, CMS sent 72 releases to drug manufacturers from 1991 through March 2006. These releases typically focused on specific definitional or calculation-related concerns.

Medicaid Reimbursement of Covered Outpatient Drugs

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations (42 CFR § 447.331(b)) require, with certain exceptions, that a State’s reimbursement for drugs not exceed, in the aggregate, the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider’s usual and customary charge to the public for the drugs. CMS allows States flexibility in defining estimated acquisition cost.

For certain drugs, States also use the Federal upper limit to determine reimbursement amounts. CMS has established Federal upper limit amounts for more than 400 drugs that meet specified criteria. Pursuant to 42 CFR § 447.332(b), Federal upper limit amounts are currently based on 150 percent of the lowest published price for therapeutically equivalent products.

States have generally based estimated acquisition cost on readily available published prices, typically the average wholesale price (AWP). OIG has found that Medicaid drug reimbursement based on AWP often exceeds pharmacies' actual acquisition costs and the prices paid by other Federal programs. AWP data have several critical flaws. AWP is not defined in statute or regulation, is not necessarily linked to actual sales transactions, and is not easily verifiable. While certain aspects of AMP need to be addressed, AMP has several advantages over AWP as a basis of reimbursement. In contrast to AWP, AMP is statutorily defined, is calculated from actual sales transactions, and is subject to audit.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

Scope

We limited our review to information obtained through OIG work since 1991 and discussions with representatives of stakeholders in the Medicaid drug rebate program (manufacturers, pharmacies, distributors, and States). The audit objective did not require that we identify or review any internal control systems.

We performed our fieldwork during March and April 2006.

Methodology

To accomplish our objective, we:

- reviewed the appropriate sections of the DRA, section 1927 of the Act, the rebate agreements between CMS and drug manufacturers, and applicable CMS releases;
- met with congressional staff to discuss the OIG requirements in the DRA;
- interviewed CMS officials;
- analyzed and compiled past and ongoing OIG work related to drug manufacturers, AMP calculations, and the use of AMP;²
- met with three manufacturer groups, three pharmacy groups, one distributor group, and one State government group to discuss their concerns related to AMP calculations and the DRA; and
- analyzed written comments provided by six of these groups.

²Many of the OIG reports contain proprietary information and are therefore not available to the public.

We conducted our review in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work has demonstrated that the manufacturers reviewed interpret AMP requirements differently. Consistent with our findings, industry groups also emphasized the need to clarify requirements. Further, they raised additional issues related to the implementation of DRA provisions. Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

SUMMARY OF OFFICE OF INSPECTOR GENERAL WORK

Our work on Medicaid drug rebates has focused on how manufacturers calculate AMP and how CMS and other agencies use AMP. Findings in these areas demonstrate the need to clarify the definition of retail class of trade and the treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales in AMP calculations. One issue fundamental to the proper treatment of PBM and other rebates is whether AMP should represent the net price realized by manufacturers or the price paid by purchasers that take possession of the drugs. Our findings also highlight the need to consider the implications of previously reported problems in the timeliness and accuracy of manufacturer-reported AMPs.

Calculating Average Manufacturer Price

Our first review, initiated in 1991, found that four drug manufacturers used three different methods to calculate AMP; they based the calculations on gross sales to wholesalers, net sales to wholesalers, or direct retail sales and retail sales reported by wholesalers. We recommended that CMS survey other manufacturers to identify the methods used to determine AMP and develop a more specific policy for calculating AMP that would protect the Government's interest and be equitable to manufacturers.

At CMS's request in the mid-1990s, we reviewed the AMP submissions of two manufacturers that had revised their AMP calculation methodologies. For the first manufacturer, we were unable to express an opinion on the revised methodology because the manufacturer lacked adequate documentation to support its changes. The second manufacturer's methodology revision primarily involved the inclusion of price concessions to customers that the manufacturer considered to be retail. For example, the manufacturer decided that price concessions to mail-order pharmacies, nursing home pharmacies, PBMs, independent practice associations, and clinics represented the retail class of trade. Based on our limited review, we disagreed with the manufacturer's designation of these customers as part of the retail class of trade; therefore, we believed that the price concessions should not have been included in AMP. However, at the time, no guidance addressed the retail class of trade issues that we reviewed. Subsequent to that review, CMS issued release 29, which provided guidance on the treatment of some of these customers.

In 2003, we initiated reviews of four manufacturers. We selected these manufacturers because they had reported to CMS that they had changed their AMP calculation methodologies and had, as a result, received State refunds of previously paid rebates. We once again found differences in the ways that manufacturers treated certain elements of their AMP calculations. As discussed below, these reviews identified significant issues related to the treatment of PBM rebates and Medicaid sales.

Treatment of Pharmacy Benefit Manager Rebates

A major factor contributing to inconsistencies in manufacturers' AMP calculations is the business relationship between a manufacturer and various groups involved in distributing drugs. PBMs, in particular, have assumed a prominent role in the drug distribution network.

Health plans and third-party payers often hire PBMs to help manage the drug benefits paid by those plans. PBMs may act on behalf of many types of customers, of which some could be considered a part of the retail class of trade. Unless a PBM has a mail-order component, it generally does not purchase drugs or take delivery of or title to the drugs.

PBMs may negotiate and receive rebates and other payments from manufacturers based on services provided (e.g., formulary development and communications to patients) and/or based on a drug's utilization or market share. PBMs may share or "pass through" to their customers some or none of the rebates or fees they receive from manufacturers. Manufacturers are generally not parties to the contracts between PBMs and their customers. Manufacturers have indicated that they may not know how much, if any, of the rebates received by a PBM are passed on to the PBM's customers. Retail pharmacy groups have indicated that PBM rebates do not get passed on to pharmacies.

Three of the four manufacturers audited as part of our ongoing work reduced their AMP values for rebates paid to PBMs. The inclusion of PBM rebates in an AMP calculation reduces AMP, resulting in lower Medicaid rebates to the States.

- Two manufacturers included all rebates paid to PBMs when calculating AMPs. One manufacturer believed that PBMs act like wholesalers because they manage the flow of drug products through their network of pharmacies. The other manufacturer indicated that, with the lack of formal guidance addressing how to handle PBM rebates, nothing precluded it from including payments to PBMs.
- The third manufacturer included a portion of its PBM rebates in the calculation of AMP based on an analysis of the health plans represented by PBMs. The manufacturer determined the percentage of health plans that it considered to be "retail," allocated rebates paid to PBMs for those plans, and included that percentage of the rebates in the AMP calculations.

Conversely, the fourth manufacturer did not include rebates paid to PBMs in its AMP calculations. This manufacturer decided not to characterize transactions with PBMs as "sales"

because PBMs do not take possession of drugs; therefore, this manufacturer believed that including the rebates in AMP would not be consistent with section 1927 of the Act.

Neither section 1927 of the Act nor the rebate agreement addresses the issue of how to treat rebates that manufacturers pay to PBMs. CMS issued three releases in 1997 that discussed PBMs. Releases 28 and 29 stated that “drug prices to PBMs” had no effect on AMP calculations unless the PBM acted as a wholesaler as defined in the rebate agreement. (CMS did not explain what it meant to act as a wholesaler in the context of PBMs, which do not typically take delivery of and title to drugs.) In release 30, CMS recognized existing confusion relating to the treatment of PBMs and stated that it intended to reexamine the PBM issue and hopefully clarify its position in the future. However, to date, CMS has not done so.

Treatment of Medicaid Sales

Another factor contributing to inconsistencies in manufacturers’ AMP calculations is the different interpretation of what sales should be included/excluded in the calculations. For example, our recent reviews found that some manufacturers excluded from the calculations a portion of sales to pharmacies that dispense prescription drugs to Medicaid beneficiaries. Two manufacturers subtracted Medicaid sales from their AMP calculations. Removing Medicaid sales from gross sales generally lowered AMP for these manufacturers.

Medicaid does not directly purchase drugs from manufacturers or wholesalers but reimburses pharmacies after the drugs have been dispensed to Medicaid beneficiaries. Because a pharmacy that dispenses drugs to Medicaid beneficiaries likely dispenses drugs to non-Medicaid patients from the same containers of the product, it would be nearly impossible for a manufacturer to specifically identify a sale that would be considered a Medicaid sale. However, two manufacturers estimated Medicaid sales amounts to subtract from the AMP calculations by multiplying the number of units that States reported when billing the manufacturer for rebates by the price the wholesaler paid for the drug.

The two manufacturers justified removing Medicaid sales for different reasons. One manufacturer indicated that because the rebate agreement did not allow a reduction of gross sales by the value of Medicaid rebates paid in calculating AMP, the sales associated with the rebates should also be excluded. The other manufacturer likened Medicaid sales to State Pharmaceutical Assistance Programs, which provide drug coverage to certain qualified individuals. CMS’s release 29 provides that sales under these programs should not be considered in AMP, so the manufacturer concluded that Medicaid sales should also not be considered.

Like Medicaid, State Pharmaceutical Assistance Programs do not purchase drugs from manufacturers or wholesalers but reimburse pharmacies for dispensing the drugs and may receive rebates from manufacturers. However, release 29 did not address the question of whether only the rebates paid to the programs should be excluded from AMP calculations (similar to the statutory requirement to exclude Medicaid rebates) or whether the underlying sales associated with the rebates should also be excluded.

We disagree with the reasoning of both manufacturers. The exclusion of Medicaid sales is not addressed in section 1927 of the Act, the rebate agreement, or any of the releases. In addition, retail pharmacies that very often dispense drugs to the Medicaid population would seem to fall squarely within the plain language of the “retail pharmacy class of trade” provision of the AMP definition.

Using Average Manufacturer Price in Reimbursement Calculations

Concerns related to AMP calculations take on additional significance given that the DRA has expanded the use of AMP. Prior to the DRA, AMP was primarily used as the fundamental component in determining the amount of Medicaid drug rebates. However, the DRA provides for the use of AMP as a basis for Medicaid reimbursement for the first time. Issues arising from the use of AMP in connection with the 340B drug-pricing program provide useful lessons as CMS (and potentially the States) prepares to use AMP as a basis for Medicaid reimbursement.

The 340B program, established by the Veteran’s Health Care Act of 1992, is a drug discount program for certain qualified covered entities (including Public Health Service and other safety-net providers) that serve vulnerable patient populations. Under the 340B program, manufacturers agree to charge participating covered entities prices that are at or below a specified maximum price (known as the ceiling price) for purchases of outpatient drugs (42 U.S.C. § 256b(a)(1)). The ceiling prices are based, in part, on the reported AMP and unit rebate amounts for covered drugs (42 U.S.C. § 256b(a)).

In our review of the 340B program, we found two primary issues that have implications for the use of AMP as the basis of Medicaid reimbursement: the timely submission of AMP data by manufacturers and the accuracy of reported AMP data.

Our review found that manufacturers did not always report AMP in a timely manner or, in some cases, did not report AMP at all.³ For example, the 340B ceiling price file for the first quarter of 2005 was missing 28 percent of the prices necessary to calculate 340B ceiling prices. For 70 percent of these missing prices, the file did not contain the AMP.

Manufacturers are required to report their drugs’ AMPs and, where applicable, the best price within 30 days after a quarter’s end so that CMS can calculate the drug’s Medicaid unit rebate amount (section 1927(b) of the Act). CMS staff reported that if the data were late, they typically contacted the manufacturers that submitted incomplete data and requested prompt submission. According to CMS, most manufacturers were responsive to these contacts and typically provided the missing data with their next quarter’s submission.

While timely submission of AMP data is important to the Medicaid rebate program, it will become even more critical when Medicaid uses AMP data as a basis for reimbursement. Late submissions of AMP data may delay, rather than prevent, State Medicaid agencies’ rebate collections. However, late submissions may prevent CMS from calculating accurate Federal upper limit prices and hinder States’ ability to accurately reimburse pharmacies.

³“Deficiencies in the Oversight of the 340B Drug Pricing Program” (OEI-05-02-00072, October 2005).

Our reviews have also found issues related to the accuracy of reported AMP data. CMS's edit of a manufacturer's AMP submission is designed to reject an AMP that is 50 percent higher or lower than the manufacturer's submission for the previous quarter. When the edit detects aberrant AMP values, CMS sends a report to the manufacturer requesting corrected information. While inaccuracies may ultimately be corrected, inaccurate AMP submissions also affect the timeliness of CMS's receipt of the correct AMPs and could affect reimbursement made before the data are corrected.

In our review of States' accountability and control over Medicaid rebate collections, we noted problems with unit rebate amounts of zero that resulted from inaccurate AMPs and the untimely reporting of AMPs.⁴ This created accountability problems in some States' administration of their rebate programs and could also create problems for reimbursement based on AMP.

SUMMARY OF INDUSTRY GROUP PERSPECTIVES

We met with eight groups that represented a cross-section of interested stakeholders, including manufacturers, pharmacies, distributors, and States, and invited the groups to provide written comments for our consideration. Six of the eight groups provided written comments. We have summarized some of their comments and suggestions below and have included their complete written comments in Appendixes A through F. We believe that the industry comments provide CMS with valuable information to use in clarifying requirements related to calculating AMP, using AMP in reimbursement calculations, and implementing provisions of the DRA.

Calculating Average Manufacturer Price

Definition of Retail Class of Trade

Consistent with our own findings, industry groups emphasized the need for clarification of entities included in the retail class of trade for AMP calculations. The manufacturer groups commented that CMS had not fully addressed which classes of trade are to be considered "retail" for purposes of calculating AMP. Release 29 clarified the retail status of some classes of trade but not all. The manufacturer groups pointed out the lack of guidance for classes of trade such as physicians, clinics, and patients (i.e., coupons or other patient discount programs).

While they agreed on the need for clarification, respondents presented different suggestions for addressing this issue. One manufacturer group suggested that the retail class of trade be defined to include only entities that dispense drugs to the general public on a walk-in basis (e.g., retail, independent, and chain pharmacies) and mail-order pharmacies that dispense drugs to patients who do not receive other specialized or home care services from the entity. Another manufacturer group did not recommend a particular definition but encouraged a definition that stipulates the criteria or rationale used to determine whether classes of trade are retail or nonretail.

The pharmacy groups advocated that the retail class of trade be limited to traditional retail outlets such as chain and independent pharmacies. These groups also believed that manufacturer sales

⁴"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048, July 6, 2005).

to mail-order and nursing home pharmacies should not be considered retail for the purposes of calculating AMPs.

The decision to include or exclude certain entities has important implications for AMP. The entities in question, i.e., physicians, clinics, and mail-order and nursing home pharmacies, may not all purchase drugs at the same price, so including or excluding sales to these entities may have the effect of decreasing or increasing AMP.

Treatment of Pharmacy Benefit Manager Rebates

Also in keeping with our findings, respondents raised issues surrounding the treatment of PBM rebates. One manufacturer group commented that CMS's limited PBM guidance had caused confusion. This group did not want any requirement that obligates manufacturers to gather information from "downstream" entities (e.g., PBM customers). The group indicated that contracts between PBMs and their customers do not have uniform provisions on the sharing of manufacturer rebates, and the group was not sure whether manufacturers could contractually require the information. Additionally, the group noted that it would be difficult to incorporate such information into AMP calculations.

The pharmacy groups and the distributor group all favored excluding PBM rebates from the AMP calculation (i.e., not subtracting rebate payments from the sales dollars) because the rebates are not passed on to the retail pharmacies.

Treatment of Administrative and Service Fees

Industry groups also sought clarification of the treatment of administrative and service fees, and respondents raised some specific points for CMS to consider in determining how to treat these fees. One manufacturer group noted that release 14 was the only guidance addressing fees and that it did not provide needed specificity. Release 14 states that administrative fees should be included in AMP if they are paid to an entity whose sales are included in the AMP calculation and if the fees ultimately affect the price realized by the manufacturer.

Another manufacturer group suggested that if CMS were to apply the average sales price criteria to service and administrative fees, it should clarify whether the definition of bona fide service is satisfied in relation to traditional wholesaler functions (e.g., pick, pack, and ship services).⁵ In addition, one manufacturer group did not want the decision to include or exclude fees to require a manufacturer to obtain information regarding transactions between downstream entities.

⁵The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the average sales price as the basis for determining reimbursement amounts for most Medicare Part B drugs. CMS guidance (question and answer 3318 on the CMS Web site at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>) indicates that administrative fees are included in the average sales price if they are paid to an entity whose sales are included in the average sales price calculation and if they ultimately affect the price realized by the manufacturer. Additionally, question and answer 4136 indicates that "bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on" to the entity's clients or customers are not included in average sales price calculations because the fees would not ultimately affect the price realized by the manufacturer. Ongoing OIG audits have shown that manufacturers treat average sales price-related administrative and service fees inconsistently.

The pharmacy groups and the distributor group, however, did not believe that these fees should be used to reduce sales values included in AMP calculations.

Including these fees would generally result in lower AMPs and, therefore, lower rebates and reimbursement (for those drugs with reimbursement based on AMP).

Lagged Price Concessions and Returned Goods

The industry groups indicated that the timing of price concessions and returned goods could create inconsistent AMPs from one period to the next, thereby creating problems with using AMP as a basis for reimbursement.

One manufacturer group stated that a methodology should be prescribed to account for late-arriving discount and rebate data. Another manufacturer group did not specifically mention lagged price concessions but commented that AMP should be calculated in such a way that would avoid the need for retroactive adjustments. The group noted that returns should be addressed. Yet another manufacturer group recommended that CMS encourage “smoothing” to accommodate transaction timing.

One pharmacy group and the distributor group recommended that lagged rebates and discounts be smoothed over a rolling 12-month period, similar to the manner in which average sales price is calculated. They also recommended that returned goods not be considered in AMP calculations.

Using Average Manufacturer Price in Reimbursement Calculations

One manufacturer group stated that AMP should not be used to set reimbursement rates until a standardized methodology for calculating AMP has been established. The group noted that the use of AMP in setting the Federal upper limits is scheduled to start January 1, 2007, but CMS is not required to issue its regulation until July 1, 2007. Another manufacturer group commented that the regulations should ensure that AMPs used in reimbursement are calculated in a way that avoids the need for restatements and unnecessary quarter-to-quarter volatility. The group also recommended that OIG caution States about potential volatility in AMP that may occur as a result of this report and CMS’s expected regulation. A third manufacturer group commented that large-volume purchasers such as large national chain drug stores could affect AMP and result in inadequate reimbursement for independent pharmacies.

The pharmacy groups expressed concern about using AMP, which was created for rebate purposes, as a benchmark for reimbursement.

Deficit Reduction Act Implementation Issues

Frequency of Average Manufacturer Price Reporting

The manufacturer groups noted that the DRA required monthly AMP reporting but did not change the quarterly rebate-reporting period in the Act. Because of this discrepancy, the groups indicated that it was unclear whether manufacturers would be required to calculate and report:

- a monthly AMP using 1 month's data;
- a monthly AMP using the most recent 3 months' data (e.g., a rolling average methodology);
- a monthly AMP using a methodology different from that used for rebate purposes;
- a quarterly AMP separate from the monthly AMPs; or
- a quarterly AMP that is an average of the monthly AMPs.

Average Manufacturer Price Restatements

One manufacturer group wanted to know whether AMP calculations would be considered final when submitted or whether manufacturers would be able, or even required, to restate their AMP calculations when they recognize that a prior AMP calculation was incorrect. Another manufacturer group asked whether AMP resubmissions would be permitted. A third manufacturer group believed that manufacturers should be able to restate quarterly AMPs, but not the monthly AMP.

Baseline Average Manufacturer Price

Baseline AMP represents the AMP calculated for the first full quarter a drug is on the open market. It is used to determine whether an additional rebate is owed to the Medicaid program. Essentially, if an AMP rises in value faster than the baseline AMP (after adjusting for inflation) the manufacturer must pay an additional rebate. Pursuant to the DRA, prompt pay discounts should no longer be considered in calculating the current quarter's AMP. Previously, section 1927(k)(1) of the Act required that prompt pay discounts be used to reduce the sales values included in the baseline AMPs. Excluding these discounts could potentially result in an increase in AMPs that exceeds the inflation adjustment, thereby triggering the additional rebate. Two manufacturer groups expressed concern that manufacturers could be penalized if baseline AMPs were not adjusted to conform to the new AMP definition. The groups indicated that manufacturers would pay an unfair amount of additional rebates related to the methodology change unless the baseline AMP is also adjusted.

One manufacturer group recommended that manufacturers be allowed, but not required, to adjust baseline AMPs. The group was concerned that a requirement to adjust baseline AMPs would be impractical for some manufacturers due to data availability and operational burden issues.

Another manufacturer group recommended that CMS work with manufacturers to develop reasonable methodologies to adjust baseline AMPs.

As a related issue, two manufacturer groups commented that any changes in AMP methodology should be made only prospectively and not retrospectively.

RECOMMENDATIONS

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of PBM rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
 - administrative and service fees,
 - lagged price concessions and returned goods,
 - the frequency of AMP reporting,
 - AMP restatements, and
 - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance.

CMS's comments are included as Appendix G. Attached to those comments were technical comments, which we addressed as appropriate.

APPENDIXES



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

March 31, 2006

Marcia Sayer
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The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide comments to the Department of Health and Human Services Office of Inspector General (OIG) regarding the content of its report to the Secretary and Congress, due June 1, 2006. That report is to contain recommendations regarding the calculation and reporting of Average Manufacturer Price (AMP) under section 1927 of the Social Security Act.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

BIO accepted the OIG's invitation to meet on March 15, 2006 to describe our views about the requirements for, and the manner in which, average manufacturer prices are determined. At that meeting, the OIG representatives requested that BIO supplement its discussion in the meeting with a written submission, by March 31, 2006. This letter responds to that request. As we noted in that meeting, the central principle of BIO's comments is that the OIG's recommendations should promote consistency, clarity, and economic fairness in the calculation and reporting of AMP.

Monthly Reporting of AMP

The Deficit Reduction Act (DRA), at section 6001(b)(1), changes the current quarterly reporting timetable for Average Manufacturer Price (AMP) and Best Price (B) to a monthly period. This monthly reporting is meant to facilitate the use of AMP figures to set monthly Federal Upper Payment Limits, or FULs, under

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DRA section 6001(a) for multiple source drugs. While the DRA did change the AMP and BP reporting timetable, the DRA did not change the statutory definition of "rebate period," i.e. the period for each state rebate claim, contained at 42 U.S.C. § 1396r-8(k)(8), which remains "a calendar quarter or other period specified by the Secretary." Given the intended use of AMPs to set reimbursement rates and the current inconsistency between the statutory reporting and rebate periods, BIO requests that the OIG's recommendations address the following issues:

1. Monthly calculation of AMP figures. The OIG recommendations should specify whether or not the new monthly timetable for reporting AMP figures also requires manufacturers to calculate AMP figures on a monthly basis, as opposed to requiring manufacturers to report a quarterly AMP figure on a monthly basis. This clarification is of paramount importance and necessary so that manufacturers can prepare for the 2007 implementation timetable.

2. The calculation methodology for monthly AMP figures. If the OIG recommends that the DRA be interpreted to require monthly calculation and reporting of AMP figures, then the OIG recommendations should also address the methodology for calculating AMP on a monthly basis. The use of monthly AMP figures to set reimbursement rates suggests that such figures, like Average Sales Price, should be final when submitted and not subject to manufacturer revisions during the three year restatement period currently permitted by regulation (42 C.F.R. § 447.534(h)(2)(i)). The OIG recommendations should address this issue. In doing so, the OIG recommendation should consider the significant added administrative burden and operational complexity that a requirement to restate monthly AMP figures would impose on manufacturers, CMS, and the States.

If the OIG recommendation is that monthly AMP figures should not be subject to subsequent revision by manufacturers, then the OIG recommendations should also address in specificity the methodology that manufacturers should use to estimate late-arriving data that is used to quantify AMP-eligible discounts and rebates and AMP-ineligible sales, the level of accuracy needed for such calculations, as well as the process for manufacturers to follow should they discover errors in previously submitted figures.¹ Whether the OIG recommends for or against the continued availability of the restatement period, given the prevalence in the industry of quarterly performance periods under discount and rebate contracts, the OIG recommendations also should address how such quarterly discount measurements should be accounted for in a monthly calculation.

¹ While the DRA does not direct the OIG to also provide recommendations regarding the calculation of Best Price, should the OIG recommend that AMP and BP figures not be subject to revision, BIO requests that the OIG also recommend a methodology for accounting for late-arriving data in the calculation of Best Price.

3. The statutory rebate period. The OIG recommendations should address whether the rebate period should continue to be a quarterly one, and if so, how the quarterly rebate amount will be derived from reported monthly AMP and BP figures.² For a quarterly rebate period, a possible solution is to require manufacturers to submit a quarterly weighted average AMP figure with its monthly submission for the third month of the quarter, with the quarterly weighted average AMP being derived from the AMPs reported for each of the months in the quarter and weighted based on AMP-eligible units for each month. Another approach would be to have manufacturers calculate monthly AMPs for the first two months of the quarter, but have the AMP for the third month of a quarter be calculated as a quarterly figure. Either approach would also provide a solution for calculating future base date AMP figures, which the Medicaid statute requires be determined based on the statute's quarterly rebate period, see 42 U.S.C. § 1396r-8(c)(2)(A), as well as for deriving Public Health Service Ceiling Prices, which federal law also requires to be derived from quarterly prices, see 42 U.S.C. § 256b(a)(2).

The OIG recommendations should also address whether manufacturers would be permitted to revise such quarterly AMP figures to reflect late-arriving data relating to AMP-eligible discounts and rebates and AMP-ineligible sales. Even if the OIG were to recommend against the availability of such revisions in relation to the AMP figures reported on a monthly basis and used to set reimbursement rates, the OIG recommendations should separately address the availability of such revisions for the AMP figures used to calculate Medicaid unit rebate amounts, and if the ability to make such revisions remains available, whether such revisions are mandatory. The continued availability of the 3-year restatement period would permit manufacturers to ensure that the AMP figures used to calculate rebate amounts are as accurate as possible and based on actual sales and discount data. However, given the added administrative burden of such revisions to both manufacturers and the States, should the OIG recommend against the availability of restatements for monthly AMP figures and direct the use of estimation methodologies for that reason, the OIG should permit manufacturers also to choose to rely on those monthly AMP figures for purposes of deriving an AMP for the rebate calculation. Manufacturers should be permitted to revise those AMP figures, to reflect late-arriving actual sales data, but not be required to do so.

4. Effective date for monthly reporting. The DRA, at section 6001(b)(1), requires CMS to begin its own monthly reporting of AMP figures to the States on July 1, 2006, using "the most recently reported average manufacturer prices." The DRA change to a monthly reporting timetable for manufacturers does not include its own effective date, and therefore appears to be governed by section 6001(g) of the DRA, which provides for an effective date of January 1, 2007

² BIO notes that any recommendation to change to a rebate period that is shorter than a quarter would require a significant implementation preparation period for manufacturers as well as the States.

where effective dates are not otherwise provided. Given the significance of this effective date to manufacturers, the OIG recommendations should confirm that that the monthly reporting obligation for manufacturers begins with the AMP and BP figures for January 2007.

5. Use of AMPs for Reimbursement Rates Prior to Issuance of Methodology Guidance. The DRA, at section 6001(a)(2), requires the use of AMP to set federal upper payment limits for multiple source drugs effective January 1, 2007, but, at section 6001(c)(3), does not require CMS to issue its rule regarding the AMP calculation until July 1, 2007. BIO believes that any AMPs used to set reimbursement rates should be calculated using a standardized methodology that is the result of input from all government and private-sector stakeholders, to ensure that the resulting reimbursement rates are fair and equitable as well as to ensure that patient access is not adversely impacted by variation in manufacturer methodology assumptions. The OIG therefore should recommend that CMS either postpone the use of AMPs to set reimbursement rates until the effective date of its rule regarding the AMP methodology, or that CMS in the short term issue interim guidance that will apply to the AMP calculation until the rule is issued and effective.

Inflation Penalty Rebate Calculation and the Prompt Pay Discount

The DRA, at section 6001(c)(1), directs that customary prompt payment discounts extended to wholesalers no longer be included as a reduction to AMP starting January 2007.³ The inflation penalty component of the quarterly rebate calculation requires the comparison of an inflation-adjusted AMP for the first full quarter of sales (the base date AMP) with the current quarter's AMP. Where the current quarter AMP exceeds the inflation-adjusted base date AMP, the difference is added to the Medicaid rebate. If customary prompt payment discounts are excluded from AMP only for the current quarter's AMP, and not also for the base date AMP, this comparison will falsely conclude that an inflation penalty is due for that proportion of the increase in the current quarter's AMP caused by the exclusion of the prompt pay discount.

The OIG recommendations should include a proposed methodology for avoiding this result. One approach would be to permit, but not require, manufacturers to recalculate their base date AMP figures to exclude customary prompt payment discounts, and to use those recalculated base date AMP figures for rebate calculations effective in 2007. The OIG should not require such a recalculation because, for certain manufacturers, data availability and the operational burden of such recalculations may make such recalculations impractical. For example, this approach would require many manufacturers to access pricing data that is many years old, stored in legacy information technology systems, and possibly relating to quarters outside of the 10 year document retention period specified in

³ The OIG recommendations should also confirm whether the definition of "wholesaler" in the Medicaid Agreement is the definition that should be used when interpreting this provision.

42 C.F.R. § 447.534(h). This approach also would require manufacturers and CMS to store and track two different base date AMP figures: one for rebate calculations relating to quarters prior to 2007 and one for quarters in 2007 and later years. As the recalculation of base date AMP would serve only to lower rebate liability, should the OIG choose this approach, manufacturers should be permitted to choose whether or not to recalculate their base date AMP figures.⁴

An alternative, and more streamlined, solution would be to revise the calculation methodology for the inflation penalty component of the rebate calculation so as to mathematically offset the impact of excluding prompt pay discounts for AMPs reported for January 2007 and later. One method for doing so would be to direct that the inflation penalty calculation include a standardized, formula-based upward adjustment to the base date AMP. For example, if the OIG were to conclude that the customary prompt payment discount percentage was 2%, then the OIG could recommend that the inflation penalty rebate calculation be adjusted to divide each reported base date AMP by .98, before applying the CPI-U based inflation factor, so as to upwardly adjust that base date AMP so that it no longer reflects customary prompt payment discounts. In this example, if the base date AMP is \$98, where it would be \$100 without inclusion of the prompt pay discounts, dividing that \$98 base date AMP by .98 will result in a revised base date AMP of \$100. This formula-based approach would have the advantage of avoiding the calculation and maintenance by CMS and manufacturers of separate base date AMP figures for rebate periods before and after 2007. This approach would also ensure that all manufacturers address this issue in the same manner.

Classes of Trade

The definition of AMP remains “the average price paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1)A(). Very little written guidance exists from CMS regarding the definition of the retail pharmacy class of trade. The OIG recommendations should define the retail pharmacy class of trade with specificity. This definition should address particular classes of entities, examples of which are discussed below, but also include the general rule that the OIG recommends be used when evaluating entities not otherwise addressed by OIG or CMS guidance. Such a general rule will provide manufacturers with a crucial baseline for use in evaluating new entity types, and will promote the important goals of consistency, clarity, and economic fairness.

⁴ If the OIG recommendation is to permit manufacturer recalculation of base date AMPs, the recommendation should also address whether the manufacturer must use the same AMP methodology the manufacturer had in place during the base date quarter. Many manufacturers have revised their AMP methodologies over time to address CMS guidance, and a legacy AMP methodology also may no longer be supported by a manufacturer's information technology. For these reasons, the OIG recommendation should permit manufacturers to use their current AMP methodology to recalculate the base date AMP.

1. Classes of trade for which guidance is needed. Current CMS guidance either does address, or does not address with sufficient specificity, the retail or non-retail status of: physicians, clinics, patients (including coupon arrangements for discounts or non-contingent free product), Part D utilization, Specialty Pharmacy, Competitive Acquisition Program or CAP sales, Pharmacy Benefit Manager mail order and retail pharmacy utilization, State Pharmacy Assistance Program (SPAP) and Medicaid program utilization, and health care plan utilization. The OIG recommendations should address each of these entity types, define each such class of trade in a manner specific enough to permit manufacturers to readily determine into which category any entity should be placed, and specify the OIG's rationale for the recommended retail or non-retail status of each class.

2. Calculation treatment of discounts and units. The OIG recommendations should specify for each class of trade the treatment of gross sales, discount dollars, net sales, if applicable, and the respective sales units associated with that class of trade. Specifically, the OIG recommendations for each class of trade should specify (1) whether gross sales, net sales, and/or discounts extended to that class of trade should be used to reduce the AMP numerator, and (2) whether the units associated with that class of trade, whether identified through sales or reimbursement transactions, should remain in the AMP denominator. This specificity is necessary to ensure clear guidance regarding treatment of a given class of trade in the AMP numerator (sales dollars) and denominator.

Additional AMP Methodology Issues

In addition to the issues identified above, BIO requests that the OIG recommendations also address the following issues:

1. Prospective application only. The OIG recommendations should specify that any clarifications and/or changes in CMS directions regarding the calculation of AMP are to be applied on a prospective basis only. The very nature of the OIG recommendations and CMS' implementation of them suggests that they are changes to existing practice, provided because of the absence of guidance in the past. These changes therefore should be prospective only. Moreover, given the complexity of the DRA changes to the AMP calculation and reporting timetable, and the operational complexity that implementing those changes presents to manufacturers, the OIG recommendations also should specify that CMS implement the DRA changes using a single, prospective implementation date that provides manufacturers with a minimum of six months lead time to make the necessary preparations.

The OIG recommendations should also include a recommendation that any and all CMS guidance in the future specify whether that guidance is to be applied prospectively and or retrospectively. Should the OIG recommend that

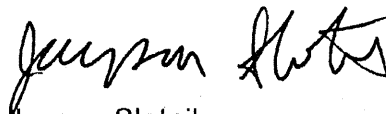
monthly AMP and BP figures not be open to revision by manufacturers during the three year regulatory period, and should CMS adopt that approach, it will be even more imperative that any future CMS guidance regarding calculation issues be prospective in application only.

2. Service and administrative fees. The OIG recommendations should address the treatment of service and administrative fees paid to entities included in the calculation of AMP. Such guidance does exist as to the calculation of ASP, in the form of two Q&As (numbered 3318 and 4136 at the FAQ link at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>). However, the existing guidance for AMP is limited to that contained in Release to Participating Manufacturers 14, and does not provide needed specificity regarding the circumstances under which such fees may and may not be included in the AMP calculation. If the OIG recommends use of the same criteria in the AMP calculation as CMS has directed be used in the calculation of ASP, the OIG recommendations should clarify whether the definition of "bona fide service" is satisfied in relation to traditional wholesaler functions such as pick, pack, and ship services.

3. Methodology change review and approval process. The OIG recommendations should also address a process and timeline for approval of manufacturer-proposed AMP methodology changes. The current CMS process is described by CMS itself as one through which manufacturers submit requests for approval, and as to which CMS provides no response or resolution. The OIG should recommend a process that details the information needed with a submission, the criteria for approval, and a deadline for CMS resolution.

In conclusion, BIO appreciates this opportunity to provide comments to the OIG regarding its recommendations to CMS as to the calculation and reporting of Average Manufacturer Price. We hope our suggestions will help the OIG to identify and provide substantive recommendations that will help manufacturers submit the data needed to calculate appropriate Medicaid reimbursement and rebate amounts for drugs and biologicals. Please contact me at 202-312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Jayson Slotnik
Director, Medicare Reimbursement and
Economic Policy
Biotechnology Industry Organization



GENERIC PHARMACEUTICAL ASSOCIATION

April 20, 2006

Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC

Re: HHS OIG study of Average Manufacturer Price

As discussed during our March 16 meeting, GPhA has concerns over the implementation of the Medicaid reform legislation. These concerns are in the areas of reimbursement methodology and program administration. We recognize that there is a need for the Medicaid Program to realize savings through the continued and expanded use of generic prescription medicines. To that end, we need to work together to ensure that all entities in the supply chain retain incentives for the continued manufacturing and dispensing of generic medicines.

Methodology for Calculating AMP:

In order to understand GPhA's concerns regarding the importance of a clearly defined methodology for calculating Average Manufacturer Price (AMP), it is important to understand the typical chain of distribution for the products of generic pharmaceutical manufacturers. Generic pharmaceutical manufacturers currently distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.). For reference, warehousing chain pharmacies include, but are not limited to, Brooks / Eckerd, CVS, Rite Aid, Walgreens, and Wal*Mart; mail order pharmacies include Caremark, Medco, and Express Scripts; and wholesalers include AmerisourceBergen, Cardinal, and McKesson. (Note: Some large chains like Walgreens and CVS also have mail order divisions.)

The legislation contemplates not only the publication of manufacturer AMP data, but also changes to the methodology for calculating. As we understand it, the AMP is intended to account for all recorded sales and discounts within the reported period; however, as you are undoubtedly aware, fluctuating order patterns and erratic timing of transactions result

in unpredictable fluctuations in AMP from month to month, or quarter to quarter based on customer mix, discount payments, returns and other normal business transactions. Moreover, given the ambiguity in the current regulatory guidance for calculating AMP, different manufacturers may very well be employing different assumptions either on their own or in conjunction with regulatory counsel to calculate their respective AMPs, which results in a variability across AMPs that prevents a true apples-to-apples comparison of pricing data across manufacturers.

It is also important to note that a manufacturer's AMP is actually a weighted average price, heavily influenced by the purchasing power of large national chain drug stores, and mass merchants. The prices paid by these volume purchasers generally are not available to others in the pharmacy community, including the independent pharmacies that portions of the Medicaid population rely upon.^{1,2} In areas where this is true, this inequity in pricing creates the potential for access to be a significant issue in the implementation of the proposed Medicaid reform. Whether sales to such volume purchasers should be included in AMP is just one of the questions raised by this legislation.

Another question concerns the legislation's current approach of using the lowest AMP reported for multi-source products upon which to base reimbursement. This model does not provide a means to measure:

1. De minimis sales volume associated with a given manufacturer's AMP,
2. A manufacturer's decision to sell a product to a single entity, regardless of volume, at a discounted price which would not represent a widely available price,
3. Discounts available to large volume purchasers based on the purchase of bulk package sizes; thereby creating a potential for reimbursement to be based on pricing that is not widely available, and in fact a statistical outlier,
4. The widespread availability to all pharmacy purchasers of certain manufacturers products,
5. The continued availability of a product for which an AMP is generated, and
6. Substantial wholesaler/distributor markup fees that apply to a majority of 30,000+ independent retailers/small chains (this subset represents almost 60% of U.S. retail pharmacy) that primarily purchase through wholesalers.

Whatever the answers to these questions, we ask only that your recommendations include a clear and concise methodology for calculating AMP that leaves no room for doubt as to the methodology that should be employed by each manufacturer in calculating AMP.

Program Administration:

In addition to the issues identified around the AMP calculation methodology, there are numerous procedural issues raised and many questions still surrounding the

¹ 2005 NCPA- Pfizer Digest

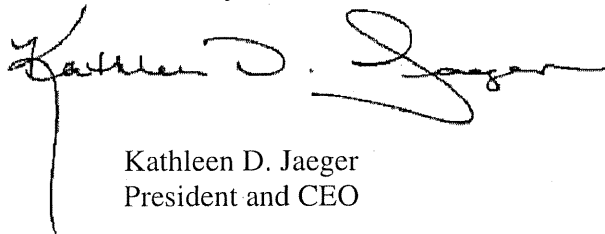
² 2005 NACDS Chain Pharmacy Industry Profile

administration of the program. As an initial matter, despite the inherent ambiguity in the current AMP calculation methodology, the legislation appears to require CMS to make public the most recent manufacturer AMP data on or about July 1, 2006. Not only does this raise the variability issues, set forth above, but publishing this data not just to the states, but to the public at large, raises serious concerns about the evisceration of the private sector reimbursement model by displaying data known to be flawed. It is one thing to demand transparency under the guise of government accountability and provide this information to the states; it is quite another to eliminate certain pro-competitive advantages that one manufacturer may have over another in the public sector by publishing a baseline price as to each product of every manufacturer. CMS has the responsibility to publish a price that accurately reflects the market, nothing more.

Moreover, as outlined above, fluctuations and timing within the generic market make AMP reporting erratic and unpredictable. This currently occurs with the existing quarterly reporting requirements, and would only be exacerbated with monthly reporting. Products with low unit volume will have a disproportionate influence on the lowest AMP than potential higher AMP products with higher unit volume. This again reflects concerns over a system not designed around a widely available price, as the current FUL. AMPs could result from pricing available only to a certain minority of providers, yet become the reimbursement standard for the total pharmacy community. "Smoothing" will also have a huge impact on AMPs due to the large dollar value of chargebacks processed for wholesaler sales for generic products. CMS has been silent on smoothing in the quarterly AMPs, although CMS does require smoothing for ASP pricing for Medicare Part B. Generic manufacturers should be encouraged to smooth data in the AMP calculation for reimbursement to accommodate transaction timing.

GPhA and its member companies appreciate the opportunity to share our concerns and thoughts with the OIG and stand ready to provide additional assistance and input as this process moves forward.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathleen D. Jaeger". The signature is fluid and cursive, with a long vertical line extending downwards from the end of the name.

Kathleen D. Jaeger
President and CEO

Attachment: Questions to Consider

Additional questions for consideration by OIG

Once more clarity exists around the AMP calculation methodology, we would like to reserve the opportunity to discuss issues identified, which may include, but are not limited to the following:

- 1) Will manufacturers be required to submit a monthly AMP for FUL and quarterly AMP for rebates?
- 2) Will the government provide class of trades for all reimbursable entities in the US, so that these codes are not subjectively assigned by manufacturers? This will ensure consistency across manufacturers when calculating AMPs.
- 3) Will AMP for FUL be calculated at the 9 or 11 digit NDC? The price would be more accurate if calculated at the 9-digit level.
- 4) Explain the exclusion of wholesaler cash discounts? Does this apply to all customers?
- 5) Explain the separate reporting requirement for cash discounts
- 6) How does a manufacturer report a negative AMP calculation for reimbursement?
Comment: For the quarterly AMP for Medicaid rebates, CMS requires that the last quarterly positive AMP be reported.
- 7) Please explain how AMP and BP are to be calculated for brands/authorized generics? Will the AG give data to the brand for the brand's submission? If so, at what level of detail? Or will CMS calculate based on the Brand and AG's submission?
- 8) Similar to current AMPs/BPs, will the supplied monthly/quarterly AMP information for each manufacturer be kept confidential, not subject to the FOIA? It could have a negative effect on manufacturers if individual AMPs were posted.
- 9) Would a manufacturer be permitted to resubmit a monthly AMP for a prior submission?
- 10) Will there be an incentive to purchase generics via dispensing fees? Will the fees be a flat dollar amount or based on a percentage of AMP?

RECOMMENDATIONS FOR REGULATIONS DEFINING AMP

EXCLUDE PROMPT PAY DISCOUNTS

RECOMMENDATION

The regulations should affirmatively state that customary prompt pay discounts are not to be deducted when AMP is calculated.

RATIONALE

The Deficit Reduction Act of 2005 (DRA) amended the statutory definition of Medicaid Average Manufacturer Price (AMP) in Social Security Act § 1927(k)(1) by deleting the requirement for “deducting customary prompt pay discounts” when AMP is calculated. HDMA understands Congress took this action because prompt pay discounts are a common practice widely accepted across many industries and should be viewed as a financial transaction representing the time value of money and risk mitigation, not as a component of the cost of the product.

Regulations affirmatively addressing the proper handling of prompt pay discounts are needed to ensure that manufacturers are alert to the statutory change in the definition of AMP that Congress chose to make by deletion. Such an alert is particularly important since the requirement to deduct prompt pay discounts from AMP has been in place since the Medicaid drug rebate program began in 1991.

The DRA includes a safeguard provision designed to ensure that the elimination of the deduction of customary prompt pay discounts from AMP is not abused in that it requires manufacturers to report on “customary prompt pay discounts extended to wholesalers” when they report AMP. This safeguard, coupled with the industry’s longstanding use of prompt pay discounts, removes the need for implementing regulations that further define customary prompt pay discounts.

EXCLUDE WHOLESALER SERVICE FEES

RECOMMENDATION

The regulations should affirmatively state that fair-market-value (FMV) fees paid to pharmaceutical distributors for distribution services that are actually provided by the distributor are not to be deducted when AMP is calculated so long as there is no implicit or explicit agreement between the manufacturer and the distributor requiring the fees to be passed on, in whole or in part, to the distributors' customers.

Service fees, derived from manufacturer – distributor negotiations, are structured in a variety of ways. The preamble to the AMP regulation should discuss factors that manufacturers and distributors should consider in determining FMV.

The preamble also should recognize that manufacturers may treat service fees as a reduction from total revenues for purposes of financial accounting even though the AMP rule instructs them not to deduct the fees when they calculate AMP.

RATIONALE

Both Finance Committee Chairman Grassley and Energy and Commerce Committee Chairman Barton stated in separate floor statements that, "It was not the intent of the conferees to suggest that by dropping bona fide service fees from the final agreement [Deficit Reduction Act of 2005] that those service fees should be included in the calculation of the Medicaid Average Manufacturer Price (AMP) reimbursement methodology as established in the pharmacy reimbursement provisions of the conference agreement."

CMS has provided guidance to the industry as a whole in the form of a Frequently Asked Question (FAQ) and directly to HDMA and Specialty Biotech and Distributors Association (SBDA) in a Dec. 9, 2004 letter, indicating that bona fide, FMV services fees should not be deducted when the Average Sales Price (ASP) is calculated. The stated rationale for the ASP instruct applies equally in the AMP context. Specifically, so long as service fees are not passed on to the distributors' customers, they "would not ultimately affect the price realized by the manufacturer."

In spite of the FAQ, manufacturers have not handled service fees consistently in their ASP calculations. Some manufacturers have elected to deduct service fees when ASP is calculated despite the FAQ instruction. These manufacturers have expressed concerns about how to determine whether fees are FMV. To avoid this same confusion in the AMP context, it is imperative for the AMP regulation itself or for the preamble to that rule to discuss how manufacturers can establish that service fees, including those set based on a percentage of associated drug costs and other services, are FMV.

Some manufactures have expressed concerns about the fraud and abuse risks associated with accounting for service fees differently for financial accounting and ASP purposes. They note that GAAP-accounting principals mandate treating fees as reductions to revenue when the fees are paid to a distributor that takes title to products and argue that failure to treat the fees as a price concession for ASP purposes creates an unacceptable disconnect between ASP reporting and financial reporting. They also note that accounting rules permit service fees to be treated as an expense on the income statement when a third-party logistics company is retained to distribute drugs without taking title to the products. As a result, these manufacturers argue that they must contract with such services rather than use traditional wholesalers to safely avoid having to deduct distribution costs from ASP, even if doing so is more costly or less efficient.

It is inappropriate and inequitable for the costs for very similar services, such as the distribution of drugs to providers, to be treated differently under a price reporting rule. There is already precedent for a similar disconnect between accounting and price reporting with respect to AMP. The IRS has ruled that Medicaid drug rebates should be treated as reductions to revenue even though the Rebate Agreement prohibits manufacturers from deducting the rebates when AMP is determined (Revenue Ruling 2005-28, published in Internal Revenue Bulletin 2005-19 (May 9, 2005)). OIG and CMS should anticipate such accounting concerns in the AMP context and address them either in the regulation or the rule's preamble, by stating that bona fide, FMV service fees are not to be deducted when AMP is calculated regardless of whether those fees are paid to wholesalers or distributors that take title or to third-party logistics companies that do not, or incurred internally by a manufacturer that self-distributes.

MINIMIZE PERIOD-TO-PERIOD VARIABILITY IN AMP

RECOMMENDATION

The regulation should specify a smoothing methodology for accounting for all price concessions in the AMP calculation in a manner like that specified for use with lagged discounts under the ASP rule. The methodology should be well-defined enough to ensure consistent treatment by all manufacturers.

RATIONALE

The current instructions for calculating AMP are silent on whether chargebacks, rebates and other lagged discounts should be accounted for on an as-paid or an as-earned basis. As a result, different manufacturers have adopted different approaches. Some use the as-paid methodology for both chargebacks and rebates. Others use as-paid for chargebacks because the amount of chargebacks paid during a period is readily available within a few days after the period closes, but use an accrual approach for rebates. Still others accrue for both chargebacks and rebates.

Many large purchasers often buy pharmaceuticals in bulk and then sell from inventory for many months. The buying pattern can result in periods when a manufacturer's sales outstrip price concessions accounted for on an as-paid basis leading to an artificially high AMP, followed by one or more periods when discounts outstrip sales, leading to an artificially low AMP. Monthly reporting of AMP likely will exacerbate this problem. If a manufacturer elects to address this problem by accounting for lagged discounts on an accrual basis, it must periodically true-up AMP and Best Price reports to address accrual errors. Such true-ups can tax the capabilities of the rebate processing teams at the state Medicaid programs as well as the price reporting teams at the manufacturers. Moreover, the true-up approach, while it does allow for the eventual payment of the correct amount of Medicaid rebates, is inconsistent with the use of AMP prospectively as the reimbursement metric that will set the Federal Upper Limit (FUL) for multiple source drugs and, possibly, by some state Medicaid programs as a

reimbursement metric in formulas that determine the payment amounts that retail pharmacies will receive for drugs dispensed to Medicaid patients.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time can also distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, OIG/CMS should implement a well-defined smoothing methodology for handling all price concessions that must be considered in AMP that operates like the methodology specified for quantifying lagged discounts under the ASP rule. If OIG/CMS are not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates despite the availability of as-paid chargeback data for a period within days after the period close because such chargebacks can often relate back to sales several periods prior.

EXCLUDE RETURN GOODS

RECOMMENDATION

The regulation should instruct manufacturers to disregard return goods when they calculate AMP.

RATIONALE

Returns to a manufacturer during a period of slow sales can actually result in a negative AMP. This, of course, is inconsistent with the use of AMP as a reimbursement metric, even for the limited purpose of setting FULs. There are two approaches to address this issue. First, as is the current CMS practice for rebate purposes, the government could revert to the last positive AMP for reimbursement purposes. Alternatively, returns could be disregarded in the calculation of AMP as they are in the ASP calculation. Given that comparisons between ASP and AMP are one of the pricing safeguards built into the ASP system, we favor the adoption of parallel rules for treating various parameters where appropriate. This would seem to be one of those situations.

PROVIDE FOR THE CALCULATION OF AMP AT 11-DIGIT LEVEL

RECOMMENDATION

The regulation should stipulate that manufacturers must calculate and report AMP at the 11-digit NDC level.

RATIONALE

Currently, in accordance with the terms of the Medicaid Rebate Agreement, manufacturers calculate and report AMP as a weighted average for a given drug, strength and dosage form across all package sizes. In other words AMP is tied to the first 9-digits of the National Drug Code (NDC) number and ignores the last two digits which represent package size.

The weighted average AMP reporting process can become problematic when the weighted average value is overshadowed by sales of one package that is significantly larger than other packages of the same drug name/strength/dosage form. The difficulty with applying the weighted average approach across all products is that physicians often dictate the package size a pharmacy must dispense. For example, a physician may prescribe a 15-gm tube of cream to treat a small rash. The price per gram for the larger 60-gm tube is typically less. Applying the 9-digit NDC price may cause an AMP-based reimbursement rate to be too low to fairly reimburse the pharmacy for the 15-gm tube.

Similarly, averaging the typically higher costs of products used extensively in long-term care (LTC) facilities (due to the added cost of packaging as unit doses) with the cost of the same product packaged for retail settings, artificially inflates the AMP of the product and simultaneously depresses the AMP for the LTC setting.

The definition of AMP in Social Security Act § 1927(k)(1), as amended by DRA, does *not* require AMP to be calculated as a weighted average across all package sizes. This approach was adopted by CMS when it

drafted the Rebate Agreement used in lieu of regulations to implement the Medicaid drug rebate program in 1991. Accordingly, CMS has the authority to change course and require 11-digit NDC-specific reporting of AMP, just like it has required 11-digit NDC-reporting of ASP. It is important to do so since States will be permitted to incorporate AMP into reimbursement formulas that will be applied to drugs dispensed to Medicaid patients by retail pharmacy.

EXCLUDE REBATES PAID TO PBMs ON RETAIL NETWORK SALES

RECOMMENDATION

The regulation should stipulate that rebates that do not reduce the effective price, such as those paid to PBMs on retail network sales, are not to be taken into consideration when AMP is calculated regardless of whether those rebates are linked to sales to Part D PDPs or MA-PD plans.

RATIONALE

Brand manufacturers typically pay rebates to pharmacy benefit managers (PBMs) for prescriptions dispensed to enrollees at retail pharmacies that participate in the PBM's retail network. The rebate payments are made to PBMs, even though the PBM does not actually purchase or dispense drugs to which the rebates are attached. Those monies are not shared with the retailers and should not be treated as a price concession that reduces AMP now that AMP will be used to set FUL and may become an element in the formulas that some state Medicaid programs use to reimburse retail pharmacies.

CMS has never issued clear guidance on how manufacturers should treat rebates paid to PBMs for retail network sales for purposes of AMP and manufacturers have adopted differing approaches.

To encourage manufacturer discounting under Part D, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 excluded rebates paid to Part D PDPs and MA-PDs, or the PBMs that operate these plans, from the calculation of Best Price. The MMA did not, however, address how Part D rebates should be handled for purposes of AMP.

CMS has historically excluded price concessions carved out of the Best Price formula from consideration when AMP is calculated and it should take a consistent approach with respect to the Part D Best Price carve out. Doing so would be consistent with the need to carve PBM retail network rebates out of AMP when those rebates are on non-Part D sales.

March 16, 2005

2006 MAR 22 AM 8:39

OFFICE OF INSPECTOR
GENERAL

March 21, 2006

The Honorable Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
Wilbur J. Cohen Building
330 Independence Ave., S.W.
Washington, D.C. 20201

Subject: Chain Pharmacy Recommendations Relating to Definition of Average Manufacturers Price (AMP)

Dear Inspector General Levinson:

The purpose of this letter is to supplement the comments that representatives of the National Association of Chain Drug Stores (NACDS) and the chain drug industry provided to staff of the HHS Office of the Inspector General (OIG) at our March 15, 2006 meeting regarding the calculation of the average manufacturers price (AMP). As you know, OIG is directed by the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171) to make recommendations to the Centers for Medicare and Medicaid Services (CMS) by June 1, 2006 regarding the factors and methods that should be included in the calculation of the AMP.

NACDS represents more than 200 companies that operate more than 35,000 community retail pharmacies. Collectively, our membership base dispenses more than 70 percent of all retail prescriptions in the United States. Our membership will be significantly impacted by the use of AMP as a reimbursement benchmark because it could result in significant underpayments for prescription medications if not accurately redefined.

In general, "AMP is the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP was created specifically in OBRA 90 to approximate the amounts that states were paying retail pharmacies for prescription drugs." In theory, the calculation of AMP is supposed to provide manufacturers with a credible value on which to base the rebates that they pay to states.

However, starting in January 2007, AMP will be used for the first time to set generic reimbursement rates for pharmacies. In addition, AMP values for single source and multiple source drugs will be made public and provided to the states starting this July. Therefore, accurate and consistent calculation of AMP is critical. AMPs must be calculated such that they are reflective of the prices at which retail community pharmacies purchase medications, or pharmacies will be underpaid for these medications.

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Although AMP has been calculated by manufacturers for over 15 years, clear direction and guidance has never been given to manufacturers by CMS. This has resulted in wide inconsistencies in these calculations. In addition, the definition of AMP has not kept pace with changes in the pharmaceutical marketplace since 1990. For example, when AMP was originally defined, there were few PBMs in the marketplace. However, rebates, discounts and price concessions given by manufacturers to PBMs and health plans have become an important component of today's pharmaceutical marketplace. In this letter, we reiterate the key points made at our meeting about the factors that we believe should be considered in the calculation of AMP.

- **Include Only Manufacturers' Sales to Wholesalers for Traditional Retail Pharmacies:** Only manufacturers' sales to wholesalers for products that are ultimately sold to traditional community retail pharmacies – traditional chain, independent, mass merchandise pharmacies, and supermarket pharmacies – should be included in the calculation of AMP. In our view, these are the only entities that should be considered the “retail class of trade.” Past audit reports done by the OIG appear to agree with that interpretation of “retail class of trade.” We also note that in CMS' final rule implementing the Medicare Part D prescription drug benefit program, the agency defines “retail pharmacy” as “any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” Thus, it would be consistent with CMS' current Part D definition of “retail pharmacy” for the agency to indicate that only sales to true retail pharmacy establishments represent the “retail class of trade” for the purpose of calculating the AMP.

Given this suggested definition, only incentive-based discounts, rebates or other price concessions that are ultimately received by retail pharmacies should be deducted by the manufacturer from total retail pharmacy sales in calculating the AMP. Manufacturers should deduct chargebacks only to the extent that they know that these were provided for products sold by wholesalers to retail pharmacies. It is fair and reasonable that only amounts paid by manufacturers that are actually passed through to retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

- **Omit Mail Order and Nursing Home Sales in AMP Calculation:** Including manufacturers' sales of pharmaceuticals to wholesalers that are eventually sold to mail order pharmacies and nursing home pharmacies is inappropriate, in our view, even though CMS has instructed manufacturers to include sales to these purchasers. That is because these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts. These discounts are either retained by the PBM, or passed through in whole or part by the PBM to the payer. They are not made available to retail pharmacies. Thus, including these sales or rebates would lower the AMP for traditional retail pharmacies below their acquisition costs.
- **Omit Rebates paid by Manufacturers to PBMs:** When AMP was originally created in OBRA 90, PBMs had little prominence in the pharmaceutical marketplace. Now, most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies.

Manufacturers should not deduct these amounts from their sales to retail pharmacies when calculating the AMP. That is because retail pharmacies do not receive these price concessions. Including PBMs' sales and discounts unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. Medicaid also loses millions of dollars each year in manufacturer rebate revenues by including these non-retail sales in the definition of AMP.

- **Omit Customary Prompt Pay Cash Discounts Extended to Wholesalers:** As defined by law (and as amended by the Deficit Reduction Act of 2005), the AMP should be calculated without regard to prompt pay cash discounts extended by manufacturers to wholesalers. Cash discounts are provided to some retail pharmacies based on financing terms negotiated between the wholesaler and the pharmacy. These are not performance-based discounts. That is, a pharmacy may receive a small discount from the wholesalers or manufacturers for paying for the drugs in a shorter period of time than other purchasers. In addition, because not all pharmacies have the distribution infrastructure (i.e. warehousing and logistical capabilities) and cash flow to capitalize on these more favorable terms, the inclusion of prompt pay cash discounts in the calculation of AMP would be inappropriate. Given that the current rebate agreement defines wholesalers as "any entity (including a pharmacy or chain of pharmacies) to which the labeler sells covered outpatient drugs...", prompt pay discounts extended to chain warehouses that are also licensed as wholesalers should also be excluded from the AMP calculation.
- **Omit Payments made by Manufacturers for Bona Fide Service Fees:** Payments made by manufacturers to entities such as wholesalers and pharmacies for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's retail pharmacy sales when calculating AMP. These payments reduce manufacturers' revenues from the sale of their drugs, but they do not lower the pharmacies' costs of purchasing prescription drugs. Moreover, not all pharmacies are able to participate in these agreements, so deducting them when calculating AMP would be unfair to many retail pharmacies. CMS has already determined that such fees should be omitted from the calculation of the "average sales price," the basis of payment for Medicare Part B drugs. Specifically, CMS has indicated that bona fide service fees are "expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer, which would have been paid by the manufacturer at the same rate had these services been performed by other entities." OIG should recommend that a similar approach be adopted for AMP.
- **Omit Manufacturer Payments for Pharmaceutical Returns:** Each year, billions of dollars in expired and recalled pharmaceuticals must be returned by pharmacies and wholesalers to manufacturers. Manufacturers issue credit to wholesalers and pharmacies for these goods. Unfortunately, the level of credit provided is insufficient to cover the products' replacement value, the pharmacy's inventory cost of carrying the product to expiration, the reverse logistics cost of returning the expired and recalled product, as well as the administrative expense incurred by wholesalers and pharmacies to manage this process. A manufacturer's payment to a wholesaler or a pharmacy for expired and recalled merchandise as well as the fees for the associated services should be excluded from the manufacturer's AMP calculation.

If these payments and service fees are included in the AMP calculation, community pharmacies will actually incur not only the deficiency in the level of manufacturer's credit for the product and service, but also a reduction in reimbursement going forward for the associated products. Payments for expired and recalled pharmaceuticals and the associated services should not be interpreted as discounts or rebates and should be omitted from the AMP.

- **Omit Manufacturer Payments for Patient Care Programs:** Many pharmacies receive payments from manufacturers for performing certain patient care services, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation. These services provide valuable benefits to patients and overall the health care system because they improve patients' understanding of their medications and enhance patient compliance. Although they reduce the revenue that manufacturers receive on the sales of these drugs, they do not reduce the retail pharmacy's cost of purchasing the drugs. If these payments are included in AMP, pharmacies would lose incentive to offer these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, not all pharmacies participate in these programs so it would be unfair to many pharmacies to include these payments in the AMP.

Because of the wide inconsistencies in the way that manufacturers currently calculate AMP, we urge OIG to recommend that CMS not make the AMP data public this July until the agency publishes a final rule that defines AMP. We believe that a great disservice will be done to states, payers, consumers, and especially pharmacies by releasing data that have wide variability in their meaning, and are likely unreflective of the approximate prices paid by retail pharmacies for prescription medications. Only when the marketplace completely understands the methodology that is used to calculate AMP, as well as its relationship to the prices paid for pharmaceuticals by retail pharmacies, should the data be made public.

We also urge OIG to make several recommendations to CMS on how the agency applies the new Federal Upper Limit (FUL) for generic drugs which, beginning in January 2007, will be based on 250% of the lowest published AMP for a generic. In order to encourage continued generic drug dispensing in Medicaid, it is critical that the FUL be based on prices for products that are currently widely available in the marketplace. For example, we believe that only a generic product that is AB-rated in the FDA Orange Book, and is widely and nationally available to pharmacies for purchase in consistent supplies, should be used as the reference product to set the FUL.

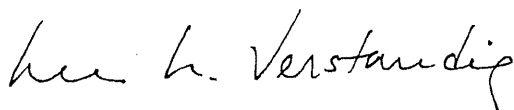
In addition, the AMP used as the reference product to set the FUL should be weighted by sales across all the package sizes of the particular dosage form and strength of the drug. The sales included in this weighted calculation should be those to retail pharmacies only. This will assure that the AMP is weighted according to the package size most frequently purchased by pharmacies. As we discussed at our meeting, we also believe that OIG should recommend that CMS adopt a process that would allow manufacturers, when calculating AMP for a quarter, to "smooth" over a rolling 12-month period of time any discounts or rebates that are passed through to retail pharmacies. This will help reduce the potential for any significant fluctuations in AMP from quarter to quarter, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturers' calculation of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement.

Without this process, it is very possible that upper limits for generics could be based on AMPs that are simply not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

Finally, to assure that generic drug dispensing in Medicaid can be maintained or even increased, we urge that the FUL amount be the minimum payment that states make for a particular dosage form and strength of a generic drug. We believe that State Maximum Allowable Cost (MAC) programs for generics should be discouraged because further reductions in state payment for generics can ultimately result in reduced generic dispensing. States should also be advised of the need to consider increases in generic drug dispensing fees for 2007 to assure that pharmacies have appropriate incentives to continue to dispense lower-cost generic drugs.

We appreciate the opportunity to meet with you and provide our views on these important issues. Please contact us if we can provide any additional insight on these specific recommendations. We look forward to reviewing OIG's recommendation and to discussing these matters further. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Lee L. Verstandig". The signature is written in dark ink and is positioned above the printed name and title.

Lee L. Verstandig
Senior Vice President, Governmental Affairs

To: OIG, HHS

From: Charlie Sewell, Vice President, Government Affairs

Date: March 16, 2006

Re: NCPA Comments on AMP provisions of Deficit Reduction Act of 2005

The National Community Pharmacists Association (NCPA) appreciates your continued interest in community pharmacy and for taking the time to meet today to discuss the issues, challenges and problems arising from implementation of the Deficit Reduction Act of 2005 ("the Act"). Most specifically, we are providing you with this comment memorandum regarding implementation of the Act and how its problematic use of a nebulously defined benchmark could have significant, harmful effects on Medicaid recipients, community pharmacies, local economies and states.

NCPA's Request:

In sum, NCPA requests that: 1) you use your authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of these major changes in the Medicaid program.¹

The Troubling Result From Using AMP:

NCPA represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies that dispense nearly half of the nation's retail prescription medicines. Because many Medicaid recipients depend on their local community pharmacies to provide them with needed medication, NCPA is compelled to alert you to language in the Act that negatively affects the costs savings that could otherwise benefit drug purchasers, States and the federal government.

As you know, the Act greatly reduces pharmacy reimbursement on generic drugs for Medicaid prescription drug recipients. The law ties reimbursement to a price index known as the Average Manufacturers Price (AMP). Leading generic drug manufacturers estimate that, as currently defined by the Manufacturers Rebate Agreement, **AMP will, on average, only reflect 50% of actual ingredient**

¹ The new Medicaid law requires that CMS disclose, starting July of 2006, the AMP pricing data to state Medicaid programs and the public. Unfortunately, the Secretary is not required to implement a regulation defining AMP until July 2007, one year after the AMP data are made public.

cost for generic drugs. Considering the unknown reliability of AMP and insufficient dispensing fees, the planned Federal Upper Limit (FUL) as contained in **the Act will effectively gut the reimbursement for generic drugs** under the Medicaid program. In stark contrast, brand name drugs are unaffected, and will be the only drugs on which pharmacists will be able to recoup their costs.

The result of promoting the use of brand name drugs over generics would be very costly. For every one percent of market share filled with a brand name drug that could be filled with a generic, Medicaid – and thus needy beneficiaries and taxpayers – will lose hundreds of millions of dollars. The lowest generic fill rate among states failing to promote generic drugs is 42%. If AMP is not correctly defined, and if dispensing fees are not increased, the potential for savings from generic drug utilization will be lost. An inadequate reimbursement level and concomitant decrease in use of generics will drive many pharmacies from the Medicaid program. Access in rural areas of the country could be particularly harmed. This resulting lack of access to quality prescription care will drive state Medicaid expenses higher as more patients require emergency room or nursing home care.

This outline of resulting harm is realistic, yet difficult to quantify. Estimating the real financial impact on retail pharmacies is extremely difficult because CMS has not publicly released AMP or issued clear guidance on how manufacturers should calculate AMP.

Based on how AMP is currently reported by manufacturers, it is clear that harmful consequences would follow from using the current AMP. NCPA respectfully urges you to use the wide statutory authority granted HHS regarding the definition of AMP to ensure that it covers 100% of pharmacists' acquisition costs. Doing so would ensure adequate reimbursements for generic drugs, thus promoting savings to the government and the health care system.

Problems With Using AMP as the Bench Mark to Determine Reimbursement Amounts and Rates:

In theory, AMP data approximates the prices at which retail pharmacies purchase medications from manufacturers via wholesalers.² For various reasons that are discussed below, however, AMP data is not at all likely to reflect the prices at which retail pharmacies purchase drugs. Because AMP was created, and is used, as a benchmark for rebate payments paid by manufacturers to state Medicaid programs, there is an inherent incentive on the part of the manufacturer to report the lowest price possible – a price that does not reflect true market costs for community pharmacy.

This fundamental problem in creating, using and monitoring the use of AMP is manifest in the following structural flaws:

- Currently, each manufacturer defines AMP differently, thus creating great inconsistencies in what is reported to CMS. In a February 2005 study (GAO-05-102), the Government Accounting Office reported that these inconsistencies are documented in the four Office of Inspector General (OIG) reports on audits of manufacturer-reported prices since the programs inception in 1991 (the reports were issued in 1992, 1995, 1997 and 2001). The GAO reported that the OIG reviews found “considerable variation in the methods that manufacturers use to determine AMP and some methods could have reduced the rebates state Medicaid programs received.” (GAO-05-102

² AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade. See 42 U.S.C. §1396r-8(k)(1). There is no definition in the statute for “retail pharmacy class of trade.”

at p.5). Furthermore, “in four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, by a lack of manufacturer documentation, or by both.” (*Id.*, p.4).

- The GAO study found that **clear guidelines on how AMP is to be calculated have not been issued by CMS, nor has CMS resolved price determination problems.** “OIG found problems with manufacturers’ price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved” (*Id.*).
 - Examples of some manufacturers taking advantage of the opportunity to alter AMP include:
 - Sales to mail order pharmacies and nursing homes when calculating AMP. Because mail order and nursing homes pay lower prices than retail pharmacies, including them in the calculation lowers the AMP below the price a traditional retail pharmacy pays.
 - Rebates paid to health plans and Pharmacy Benefit Managers (PBMs) when calculating AMP. These discounts are typically extended to bulk purchasers such as chain pharmacies, major wholesalers, and mail-order facilities that buy directly from the manufacturer. These discounts are simply not available to independent pharmacies, further widening the gap between AMP and market price.
 - These price concessions, however, are not available to retail pharmacies and therefore do not lower the pharmacies’ costs of purchasing prescription drugs. Including PBMs’ sales and discounts may lower the AMP to a level that does not reflect the cost to a retail pharmacy.
 - As the manufacturer must pay rebates based on AMP, the manufacturer then has an incentive to report the lowest numbers possible.
 - Wholesaler costs and margins will not be covered by AMP. Federal law also makes few provisions for state determined dispensing fees which will become critical in ensuring that the professional services of pharmacists remain available to Medicaid patients.
 - State MAC lists currently are lower than the FUL – significantly lower for some products and in some states. If states follow their current practice, often states will reimburse below the 250%. A study is needed to evaluate what currently happens and to find out how much below 250% of AMP states are reimbursing.

Conclusion:

Since all reimbursement cuts will come from generic prescription drugs, the AMP must be defined to cover acquisition costs or a perverse incentive will be created to dispense brands that could end up costing the program much more. To avoid the drastic consequences employing AMP in a situation for which it was not designed, NCPA respectfully requests that you recommend that: 1) HHS use its authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the major changes in the Medicaid program.



April 7, 2006

VIA HAND DELIVERY AND E-MAIL

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Average Manufacturer Price Recommendations

Dear Mr. Levinson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide the following information on the determination of Average Manufacturer Price (AMP) in response to the Office of Inspector General's (OIG's) request for input on these issues. PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in working with the government to develop clear and carefully-considered rules on the calculation of Medicaid rebates and the reimbursement of pharmaceutical products. Given this interest, and the Government Accountability Office's (GAO's) finding that clearer guidance is needed regarding AMP calculations,¹ we were pleased that Congress recently charged the OIG with reviewing "the requirements for, and manner in which" AMP is determined and submitting any recommendations it considers appropriate "for changes in such requirements or manner" to the Centers for Medicare and Medicaid Services (CMS) and Congress.² We believe this mandate provides an important vehicle for helping to improve the clarity and

¹ GAO, Medicaid Drug Rebate Program, Inadequate Oversight Raises Concerns about Rebates Paid to States, GAO-05-102, 4 (Feb. 2005).

² Deficit Reduction Act of 2005, P.L. 109-171, § 6001(c)(3) (2006). Following its receipt of the OIG's recommendations, CMS must issue regulations clarifying AMP calculations, taking into consideration the OIG's recommendations, by July 1, 2007.

Pharmaceutical Research and Manufacturers of America

950 F Street, N.W., Washington, D.C. 20004 • Tel: 202-835-3500

consistency of AMP calculations, which will now, in addition to affecting Medicaid rebates, affect pharmacies' Medicaid reimbursement rates for certain pharmaceuticals.

We appreciate the recent opportunity OIG provided to PhRMA to meet and discuss these issues, and we have focused our written comments on several of the issues raised by OIG during that meeting. Specifically, our comments address the following topics: the function of AMP, defining the "retail pharmacy class of trade," the ability to capture transactions between downstream entities in manufacturers' AMP calculations, the timing and application of changes in AMP, the issues associated with using AMP as a reimbursement metric, and the frequency of AMP reporting. These comments are preceded by general principles that PhRMA hopes the OIG will consider as it develops recommendations concerning the methodologies and manner in which AMP is calculated.

- As a general matter, AMP calculations should result in a calculated price that represents the amount realized by the manufacturer for product sold and distributed to wholesalers in the relevant period for purchasers who are in the retail pharmacy class of trade.
- Guidance concerning the calculation of AMP should be formalized in regulations that give stakeholders adequate opportunity for notice and comment.
- CMS should apply its regulations prospectively and give manufacturers ample time to operationalize systems, policies, and procedures to support the new AMP calculation.
- CMS should issue regulations to ensure that AMPs that now will be used in reimbursement formulas are calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts; and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims.
- Any procedures developed by CMS should recognize that there may be instances that call for restatements of AMP notwithstanding efforts to ensure the accuracy of reported data.
- Because the DRA changes the definition of AMP, CMS should develop a mechanism to conform baseline AMPs to the revised statutory definition of AMP for purposes of the additional rebate.

* * *

A. Retail Pharmacy Class of Trade

AMP is defined by statute as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”³ As Congress recognized in the Deficit Reduction Act of 2005 (the DRA) when it directed the OIG to develop recommendations, and CMS to issue regulations concerning AMP, there is a need for clear and consistent guidance concerning the definition and calculation of AMP. This need for clarity is particularly critical given the use of AMP to establish Medicaid drug rebates. Moreover, it will take on even greater significance because AMP also will be used to establish upper payment limits for State Medicaid prescription drug payments beginning in 2007. Notably, the statute does not define AMP as a metric that approximates pharmacy acquisition costs. As discussed above, AMP is defined as the “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”⁴ The statute does not define AMP as retail pharmacy acquisition costs. Moreover, Congress further demonstrated its understanding that AMP does not directly measure pharmacies’ acquisition costs when it chose to apply a 2.50 multiplier to establish FULs for multiple source drug products.

CMS has issued guidance previously regarding the definition of AMP in the Medicaid Rebate Agreement, certain Medicaid Rebate Releases, and proposed rules, but it has not defined the term “retail pharmacy class of trade” or provided a comprehensive listing of which entities fall inside and outside the retail pharmacy class. The language in the Rebate Agreement bearing on this issue provides that:

[AMP] means . . . the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP.⁵

In the preamble to proposed (but never finalized) regulations published in 1995, CMS similarly stated that:

[S]ales that a manufacturer makes to other than the retail class of trade must be excluded [from AMP]. Thus, sales where the buyer relabels or repackages the drug with another NDC number and sales through wholesalers where the manufacturer pays a chargeback for sales to an

³ 42 U.S.C. § 1396r-8(k)(1). Under the DRA section 6001, customary prompt pay discounts extended to wholesalers will be excluded from AMP calculations by 2007.

⁴ Id.

⁵ Medicaid Rebate Agreement, § 1(a), *available at*, <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf>.

excluded buyer, such as a hospital, would not be considered sales to the retail class of trade.

We would also exclude from this definition direct sales to hospitals, health maintenance organizations and to distributors where the drug is relabeled under that distributor's NDC number because these entities are not considered the retail pharmacy class of trade. We would also exclude Federal Supply Schedule (FSS) prices from the calculations of AMP since the statute does not include FSS and FSS does not represent a retail level of trade.⁶

Finally, in Medicaid Rebate Release 29 (1997), CMS listed certain categories of sales as either included in or excluded from AMP. Specifically, the release provided that: (1) AMP includes mail order and retail pharmacy sales, "nursing home primary/contract pharmacy sales," and "sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC"; (2) AMP excludes direct sales to hospitals, HMO sales, Public Health Service (Section 340B) covered entity sales, "state-funded only-pharmacy assistance programs," "VA/DoD excluded sales," Federal Supply Schedule sales, and "sales to other manufacturers who repackage/relabel under the purchaser's NDC"; and (3) sales to wholesalers are included in AMP "except for sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories."⁸ Although Release 29 clarified some issues, it did not address a variety of entities and arrangements that could affect the calculation of AMP. Moreover, Release 29 is likely outdated given the continuously evolving nature and functions of various entities in the pharmaceutical distribution chain.

For example, CMS has not specified whether other specific categories of sales are included in or excluded from AMP. Some of the customers not addressed in Release 29 include, for example, physician groups, clinics other than Section 340B covered entities, and patients (i.e., there is no guidance on whether patient coupons or other patient discount programs affect AMP calculations).⁹ There has also been a lack of clear guidance regarding whether rebates to PBMs or payors (including Medicare Part D plans) should be excluded from AMP calculations, and (if so) whether manufacturers should simply exclude the rebates themselves from AMP calculations or should remove from the AMP numerator and denominator the underlying sales to wholesalers to which the rebates are attributed.

⁶ 60 Fed. Reg. 48442, 48462 (Sept. 19, 1995).

⁷ The Rebate Agreement defines a "wholesaler" as "any entity (including a pharmacy or chain of pharmacies) to which the [manufacturer] sells the Covered Outpatient Drug, but that does not repackage or relabel the Covered Outpatient Drug." Rebate Agreement, § 1(ee).

⁸ Rebate Release No. 11 (1994) also states that "sales of hemophilic drugs to home health care providers must be included in the calculation of AMP," indicating that home health care providers would be considered part of the retail pharmacy class of trade. (Emphasis omitted.)

⁹ CMS has issued guidance on this topic in the Best Price context.

As a result of the unaddressed questions regarding the “retail pharmacy class of trade,” the GAO found that manufacturers made different assumptions about which entities were considered within the class.¹⁰ Consequently, to reduce manufacturers’ uncertainties and increase the consistency of AMP calculations, it will be important for the OIG to make strong recommendations regarding the clarification of these definitional issues.

In an evolving marketplace, terms such as “wholesaler” and “retail” may be interpreted in different ways by different companies and entities. Entities are more appropriately categorized for purposes of defining AMP by the actual functions they perform rather than by the names by which they generally are known at any given time. Thus, PhRMA believes that an optimum approach is to use function-based analysis that recognizes that the function of an entity in the distribution chain may govern whether particular transactions should be included in the calculation of AMP. We suggest the following function-based definitions for the key AMP terms: “wholesaler” and “retail class of trade.”

- i. **Wholesaler** shall mean those entities that purchase covered outpatient prescription drugs as defined in Section 1927(k) directly from the manufacturer, or its authorized agent, and that take legal title to the prescription drug product.
- ii. **Retail Class of Trade** (a) shall mean, subject to subsection (b), those entities or such subdivisions, departments or lines of business that:
 - 1. dispense covered outpatient drugs to patients, who are members of the general public on a walk-in basis, pursuant to a prescription, including for example, retail, independent, and chain pharmacy;
 - 2. dispense covered outpatient drugs to patients through the mail (or other common carrier) pursuant to a prescription and the patient does not receive other specialized or home care services in addition to the dispensed drug;

and (b) shall not include such entities or such subdivisions, departments or lines of business that:

- 1. only dispense covered outpatient drugs to inpatients of the entity (e.g., inpatient hospitals);

¹⁰ GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concern, at 16.

2. administer the drug "incident to" a physician or other licensed prescriber's services' (e.g., physician offices);
3. dispense only to a defined and exclusive group of patients who have access to dispensing services (e.g., closed pharmacy, staff model HMO, or correctional facility);
4. are federal, state, or local government purchasers and those purchasing under the federal supply schedule (e.g., VA);
5. are exempt from best price (e.g., 340B entity, SPAP, Part D Plans);
6. are other wholesalers or distributors that do not dispense to patients;
7. negotiate or arrange for pricing terms for third parties but that do not take possession of the drug product (e.g., GPO);
8. repackage or relabel under the entity's own NDC; or
9. are entities to which sales below 10% of AMP are considered to be nominal sales under Section 1927(c)(1)(D).

All parenthetical examples are for illustrative purposes and manufacturers may document that sales to such an entity should be included or excluded in the retail class of trade based on its function in a manner that differs from the illustrative example. Two areas where it would be helpful for the OIG to provide recommendations concern the application of these functional standards to long-term care facilities, PBMs, and other entities that reimburse for drugs but do not take title or possession of the drug product.

B. Taking Into Account Transactions Between Downstream Entities in AMP Calculations

In PhRMA's recent meeting with the OIG, the OIG expressed interest in obtaining additional information on the pharmaceutical distribution chain and the flow of payments within the pharmaceutical system. The OIG also indicated that it was interested in this information on the pharmaceutical supply chain and payment system partly in order to gain an understanding of whether manufacturer payments were passed through by their recipients to other parties. In addition, the OIG asked whether it would be feasible for manufacturers to require contractually that recipients of

payments inform the manufacturer about whether the payments had been passed through to others.

As noted at the meeting, PhRMA does not obtain information on member companies' pricing practices due to antitrust concerns, and information on pricing and payment arrangements between many of the participants in the pharmaceutical system is closely held and generally unavailable to manufacturers in any case. However, we have included in the appendix a brief general overview of the pharmaceutical distribution chain and payment system, based on information from publicly available reports.¹¹ In addition, we address the question raised in the meeting about the feasibility of requiring contractual reporting of downstream payments.

In past guidance, CMS has sometimes suggested that whether a certain manufacturer payment should be taken into account in the manufacturer's pricing calculations may depend on whether the payment is passed through by its recipient to another party.¹² In recent Average Sales Price (ASP) guidance on service fees paid to buyers, CMS stated that "[b]ona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on in whole or in part to a client or customer of an entity" should be excluded from ASP because "these fees would not ultimately affect the price realized by the manufacturer."¹³ However, the ASP analysis may not adequately capture the fluid nature of certain transactions with and among downstream entities or the role of different entities in the distribution chain. Accordingly, PhRMA believes that OIG and CMS should clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities.¹⁴ We believe that such a requirement would create serious problems and urge the OIG not to recommend this approach. Manufacturers have no authority to demand that payment recipients disclose to the manufacturer whether they have shared the payment in question with their own customers or clients, and there is no guarantee that payment recipients would agree voluntarily to such disclosures. The payment recipient might reject such disclosure provisions due to, for example, concerns about its ability to

¹¹ Our discussion is based exclusively on publicly available sources cited in the appendix. Principal among the sources are (1) Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies*, Aug. 2005 (FTC report); (2) *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, report prepared for The Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005 (*Follow the Pill*); (3) *Navigating the Pharmacy Benefits Marketplace*, report prepared for the California HealthCare Foundation by Mercer Human Resource Consulting, Jan. 2003 (*Navigating the Pharmacy Benefits Marketplace*); (4) *Study of Pharmaceutical Benefit Management*, report by PricewaterhouseCoopers LLP for the Health Care Financing Administration, June 2001 (PricewaterhouseCoopers report); and (5) Department of Health and Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices*, April 2000 (HHS report).

¹² CMS alluded to pass-through issues in its rebate guidance on PBMs (which has caused interpretive difficulties), stating in part that "where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations." *Medicaid Rebate Release No. 29* (1997).

¹³ CMS Frequently Asked Question ID 4136 (last updated Feb. 14, 2006).

¹⁴ At the same time, OIG and CMS should recognize the need for clear guidance concerning these transactions and their role (if any) in AMP calculations.

preserve the confidentiality of this competitively sensitive information once it was routinely disclosed to manufacturers; concerns about the administrative burdens associated with such reporting obligations; or concerns about the potential liability risks associated with furnishing manufacturers with information that would be used in the manufacturer's AMP calculations, and that could thus result in incorrect rebate payments and Medicaid reimbursement rates if the information turned out to be inaccurate in some respect. Consequently, manufacturers simply might be unsuccessful in negotiating contractual provisions requiring disclosure of pass-through information, or they could experience prolonged delays in negotiating contracts important to their ability to sell products or to acquire needed services.

Moreover, even if manufacturers could negotiate and enforce pass-through reporting provisions, the resulting information could be difficult to incorporate into a manufacturer's systems for calculating and reporting AMP. As discussed in the appendix, for example, PBMs' contracts with their clients do not have uniform provisions on the sharing of manufacturer rebates. To report whether the rebates paid by a manufacturer for a specific quarter were passed through, the PBM might need to determine the clients to which those rebates were attributable and separately identify pass-through and non-pass-through rebates. In turn, the manufacturer could not rely on a standard protocol specifying that (say) PBM rebates are taken into account in AMP calculations; instead, each AMP-reporting period, manufacturer personnel would need to review each PBMs' disclosure report and make case-by-case decisions about the appropriate treatment of PBM rebates in the AMP calculation. These kinds of frequent manual interventions in the AMP-calculation process could substantially increase the complexity of these calculations and heighten the risk of error, thus making it difficult for manufacturers to provide CMS with accurate AMP data on a timely basis. Similarly, delayed pass-through reports from payment recipients could complicate AMP calculations and cause overly burdensome restatements in previously reported AMP figures.

Given the problems with requiring that manufacturers contract with customers to obtain information on pass-through issues and then incorporate that information into their AMP calculations, we urge the OIG to recommend that CMS not adopt such an approach.

C. Other Issues

During PhRMA's meeting with the OIG on March 16th, PhRMA raised a number of issues concerning implementation of the AMP provisions in the DRA and changes to the definition and methodology used to calculate AMP. PhRMA's written comments and recommendations concerning several of these issues are set forth below.

1. Conforming Baseline AMPs to the New AMP Definition

The “additional rebate” for innovator drugs equals the current-period AMP minus the inflation-adjusted baseline AMP (usually the AMP from the first full quarter after launch).¹⁵ Because the DRA changes the definition of AMP, it raises the question of what mechanism should be used to conform baseline AMPs (as of the quarter when the AMP definition changes to exclude prompt pay discounts) to the revised statutory definition of AMP. The OIG may wish to recommend that CMS work with companies to develop reasonable methodologies to make this correction.¹⁶

2. Prospective Application of Clarification of AMP Guidance

The OIG should recommend that CMS issue regulations and guidance that make only prospective changes in AMP calculations. This recommendation would be consistent with the DRA, which calls for regulations that clarify “the requirements for, and manner in which, average manufacturer prices are determined,” not were determined in the past, and would recognize GAO’s finding that manufacturers have historically had to rely on reasonable assumptions in certain areas due to the absence of clear guidance.¹⁷ Prospective application of changes to AMP calculations would also avoid the difficulties and disruptions associated with industry-wide retrospective recalculations of past period AMPs.

3. Timing Issues Associated With Changes in AMP

The DRA contains a number of AMP-related provisions that take effect (or have deadlines) at different dates, which could result in a series of sequential changes to AMP calculations unless CMS makes an effort to synchronize the changes.¹⁸

Recognizing that manufacturers need sufficient lead time to change their systems and collect any additional data that may become relevant to AMP calculations, OIG should issue a recommendation that CMS provide adequate phase-in periods for any changes in AMP. The OIG also should recommend that CMS issue proposed and final AMP regulations as promptly as possible and seek to avoid a series of sequential changes in AMP calculations; frequent changes in AMPs due to a series of regulatory

¹⁵ See 42 U.S.C. § 1396r-8(c)(2).

¹⁶ We note that any changes in the existing requirements for calculating AMP that CMS adopts in its regulations on AMP calculations could raise similar questions regarding the baseline AMP.

¹⁷ DRA § 6001(c)(3). (Emphasis added.)

¹⁸ Some of the relevant dates for DRA AMP provisions are: June 1, 2006 (deadline for OIG recommendations regarding the requirements for and manner in which AMP is determined); July 1, 2006 (CMS must provide AMP data on a website accessible to the public); January 1, 2007 or earlier (AMP definition changes to exclude customary prompt pay discounts extended to wholesalers); January 1, 2007 (DRA section 6003 takes effect, which modifies the AMP definition “[i]n the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act”); and July 1, 2007 (deadline for CMS to issue regulations on AMP).

changes could heighten instability for providers that receive AMP-based payments for multiple source drugs, confuse the public (which will soon have access to AMP data), and require repeated changes in manufacturers' data collection and reporting systems. Similarly, the OIG may wish to caution manufacturers that changing their AMP reporting systems in response to the OIG recommendations could exacerbate these problems, as the final AMP regulations issued by CMS could differ from the OIG recommendations, and require that manufacturers adopt a different set of changes in AMP calculations.

4. Issues Associated With Using AMP as a Reimbursement Metric

Effective January 1, 2007, the DRA bases the Medicaid federal upper limit for multiple source drugs on AMP. Any recommendations or regulations should ensure that AMPs that are used in reimbursement formulas can be calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts;¹⁹ and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims. This could raise issues regarding AMP similar to issues that have been raised in the context of ASP (the drug reimbursement metric generally used under Medicare Part B).²⁰ Notwithstanding efforts to ensure the accuracy of reported data, there may be instances that call for restatements of AMP. This raises a dilemma given AMP's new role as a reimbursement metric, because the restatement could occur after a state has set the AMP-based reimbursement rates for a particular period. The OIG may want to formulate recommendations on a method for resolving this dilemma.

Moreover, the OIG also may wish to caution the states about the potential volatility associated with using AMPs that may change substantially due to sequential changes that will occur as the OIG issues recommendations in June 2006, and CMS issues a regulation by July 2007, concerning the new definition and clarification of AMP.²¹

5. AMP Reporting Frequency Issues

Section 6001 of the DRA appears to amend SSA § 1927(b)(3)(A)(i) to call for monthly reporting of AMP and Best Price.²² However, section 6003 then strikes section

¹⁹ Zero or negative amounts should not be an issue under existing CMS guidance, which provides that if a zero or negative AMP occurs in a given quarter, the manufacturer should report the last calculated AMP with a value greater than zero. Medicaid Rebate Release No. 38 (1998).

²⁰ As in the ASP context, returns should also be addressed.

²¹ The DRA requires the Secretary to make available to the states the AMPs for single source and multiple source drugs beginning in July 1, 2007. These AMPs may be substantially different from AMPs calculated after January 1, 2006 because of the newly promulgated definition of AMP which now directs manufacturers to exclude prompt pay discounts to wholesalers. Moreover, AMPs may change as a result of OIG's recommendations (due in June 2006) and CMS regulations (due July 1, 2007).

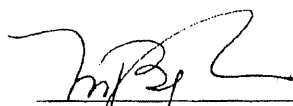
²² Section 6001(b)(1)(A) amends Social Security Act § 1927(b)(3)(A)(i) to state that manufacturers with rebate agreements shall report AMP and Best Price to the Secretary "not later than 30 days after the last day of each month of a rebate period under the agreement" (Emphasis added.)

1927(b)(3)(A)(i) and replaces it with new language that refers to AMP and Best Price being reported "not later than 30 days after the last day of each rebate period."²³ Thus, it appears that the law did not effectively change the frequency of manufacturers' reporting obligations. In the event that the DRA were to be interpreted to call for monthly reporting of AMP and Best Price, a number of issues would arise, and it may be helpful for OIG to develop recommendations on these points should they become relevant. OIG should recommend how quarterly rebates should be calculated and should recommend against basing rebates on weighted averages of monthly AMPs. In addition, OIG should recommend that restatements of quarterly AMPs continue to be permitted and that any monthly AMPs (should the statute ultimately be interpreted to require such calculations) not be restated.

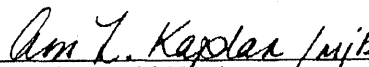
* * *

PhRMA hopes that these comments will be helpful to the OIG as it formulates its recommendations to CMS and the Congress regarding AMP reporting and looks forward to providing additional input. We appreciate the time taken by OIG staff to meet with us and consider our comments, and the substantial effort your office is making to develop recommendations that can lead to clearer ground rules for AMP reporting and an improved system. Please do not hesitate to contact us with any questions or requests for additional information.

Sincerely,



Maya J. Birmingham
Assistant General Counsel



Ann Leopold Kaplan
Assistant General Counsel

²³

DRA § 6003(a)(1).

Appendix

Overview of the Pharmaceutical Payment System²⁴

While there is variation in the way that prescription drugs are distributed, the payment and pricing system is much more complex than the distribution system, and continually is evolving. Partly this increased complexity is because payment and pricing arrangements involve additional parties that generally do not play a role in the physical distribution of pharmaceuticals: in particular, PBMs and payors. As summarized in one report, “while the flow of products through the pharmaceutical chain is relatively straightforward, the flow of money involves a wider range of players and complex financial relationships.”²⁵ The discussion below begins with a general summary of the payment arrangements between the key entities involved in the distribution chain — manufacturers, wholesalers, and pharmacies — and then briefly describes some of the other participants in the payment system and the roles they play.

As noted earlier, manufacturers most commonly sell to wholesalers that resell to pharmacies. Manufacturers’ list prices to wholesalers are known as wholesale acquisition cost (WAC).²⁶ Wholesalers typically purchase at a discount off of WAC²⁷; examples of discounts for branded products include prompt pay discounts, volume discounts, and “short-dated” product discounts (where the wholesaler assumes the risk that the product will expire before it can be resold).²⁸ In recent years, the major wholesalers have sought to move to a “fee-for-service” model in which they negotiate fees with manufacturers for activities such as distribution and inventory management.²⁹

Pharmacies that purchase from wholesalers pay an amount negotiated with the wholesaler. According to one report, pharmacies typically pay wholesalers WAC plus some negotiated percentage.³⁰ In some cases, pharmacies or other “end-user” customers that purchase through wholesalers may negotiate rebate agreements with manufacturers, or they may negotiate a contracted price with the manufacturer. When

²⁴ As noted earlier, this appendix provides a brief general overview of the pharmaceutical distribution chain and payment system based on information in publicly available reports. Particularly given the complexity of the payment system, there may be arrangements or practices not captured in these reports.

²⁵ Navigating the Pharmacy Benefits Marketplace at 18.

²⁶ As defined in the Medicare Modernization Act, WAC represents “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug and biological pricing data.” Social Security Act §1847A(c)(6)(B).

²⁷ Follow the Pill at 18.

²⁸ Id.

²⁹ See, e.g., R. David Yost, New Economics of the Pharmaceutical Supply Chain, 62 Am. J. Health-System Pharm. 525 (March 2005).

³⁰ Follow the Pill at 18.

wholesalers sell to customers that have a contract price with a manufacturer, they charge the contract price and then bill the manufacturer for a "chargeback"; the chargeback equals the differential between WAC and the contract price.³¹

Smaller pharmacies also may use group purchasing organizations (GPOs) in some cases to negotiate prices with wholesalers or manufacturers.³² GPOs are entities that negotiate discounted prices on behalf of their members (which primarily are hospitals and other healthcare providers) from manufacturers and distributors of pharmaceuticals and other healthcare products. Pharmaceutical manufacturers and other vendors pay administrative fees to GPOs, which (at least in the case of six GPOs that were studied by the OIG) distribute a portion of their administrative fee revenues to their members.³³

PBMs play a number of roles in the pharmaceutical payment system. Normally PBMs are not directly involved in the product supply chain, since they do not take physical possession or control of pharmaceuticals as part of their core pharmacy benefit management functions.³⁴ However, many PBMs own and operate mail order pharmacies and (in their capacity as mail order pharmacies) buy drugs from wholesalers or manufacturers and dispense them to patients.³⁵

PBM clients can generally be described as "payors." That is, a PBM's clients usually are entities that provide prescription drug insurance to their enrollees or members, such as self-insured employers, insurers, and HMOs and other managed care organizations.³⁶ The specific services a PBM performs will vary depending on its contract with particular clients, but PBM functions generally include forming pharmacy networks and negotiating discounted reimbursement rates with network pharmacies; developing and administering formularies and related features of the plan design (e.g., formulary tiering structures, utilization management tools such as prior authorization); negotiating rebates with manufacturers; and processing claims.³⁷

Payments that PBMs negotiate with manufacturers of brand-name drugs include rebates, and administrative fees that compensate the PBM for formulary-related administrative activities.³⁸ The effect of manufacturer rebates to PBMs on

³¹ Id. at 19.

³² Navigating the Pharmacy Benefits Marketplace at 25; Follow the Pill at 19-20.

³³ See HHS OIG, Review of Revenue From Vendors at Three Group Purchasing Organization and Their Members, A-05-3-00074, Jan. 2005 (the GPOs studied collected \$1.8 billion in administrative fee revenue during the audit period and distributed \$898 million to members); HHS OIG, Review of Revenue From Vendors at Three Additional Group Purchasing Organizations and Their Members, A-05-04-00073, May 2005 (GPOs studied collected \$513 million in administrative fee revenue during the audit period and distributed \$217 million to members).

³⁴ Follow the Pill at 14-15; FTC report at 7.

³⁵ Follow the Pill at 14-15; FTC report at 5-6.

³⁶ FTC report at v; PricewaterhouseCoopers report at 17. In some cases, these entities can be purchasers of drugs as well as payors; for example, some "staff model" HMOs operate on-site pharmacies at their facilities.

³⁷ See, e.g., PricewaterhouseCoopers report at 50-58.

³⁸ See, e.g., FTC report at 50-55. In some instances manufacturers also may pay PBMs fees for compliance, therapeutic interchange, and other programs related to particular drugs. Id. at 55. In addition to entering into

pharmaceutical prices has been described as follows: "This rebate does not affect the price paid by a wholesaler to a manufacturer for the drug, the price paid by a retail pharmacy to the wholesaler, or the price paid by the PBM to the pharmacy. It is a separate transaction between the PBM and the manufacturer and thus affects the total amount spent by the PBM. To the extent that a portion of the rebate is passed along, the insurer, employer, or beneficiary may realize a part of these savings."³⁹

Both the FTC's recent study on PBMs and an earlier study by PricewaterhouseCoopers reported that PBMs commonly pass through a share of manufacturer rebates, but not administrative fees, to their clients.⁴⁰ In addition, both studies indicated that the share of rebates passed through to a PBM's clients varies considerably from contract to contract.⁴¹ For example, the FTC examined the retention rates for all pharmaceutical manufacturer payments (including non-pass-through administrative fees) on 11 PBM contracts, and found that in 2003 the PBMs' retention rates on these contracts ranged from 25% to 91% (i.e., pass-through rates ranged from 75% to 9%).⁴² The PricewaterhouseCoopers study reported that the percentage of rebates PBMs share with their clients can range from zero to 100%.⁴³

The FTC also noted that the percentage of manufacturer rebates that a PBM passes through to a client cannot be viewed in isolation, because clients make payments to PBMs (e.g., administrative fees for claims processing and other services, and reimbursement for the drugs dispensed to plan beneficiaries) and a client could negotiate lower payments in exchange for receiving a lower percentage of manufacturer rebates. Thus, "PBMs could adjust any of a number of terms (e.g., dispensing fees, discounts off of ingredient costs) to make the contract more attractive to plan sponsors" and "in this way manufacturer payments to PBMs could be passed on to plan sponsor clients through a complex array of adjustments to contract provisions relating, for example, to the services that would be provided by the PBM and the prices and fees that would be paid by plan sponsor clients."⁴⁴

agreements with PBMs providing for rebates and administrative fees, manufacturers may enter into similar agreements with insurers or other health plan sponsors that manage their own drug benefits, as well as with public programs that provide drug coverage.

³⁹ HHS report at 104.

⁴⁰ PricewaterhouseCoopers report at 9, 16, 52; FTC report at 59.

⁴¹ The FTC found that PBMs and their clients have agreements with three different types of rebate sharing models. In addition to contracting for a certain percentage of manufacturer rebates, PBM clients may also negotiate arrangements in which they receive a specific dollar amount per brand-name drug prescription from the PBM rather than receiving a share of the actual rebates paid to the PBM, or arrangements in which they receive a specified share of rebates subject to a guaranteed minimum rebate payment. FTC report at 57-58.

⁴² FTC report at 59.

⁴³ PricewaterhouseCoopers report at 88. See also HHS report at 105 (noting that industry sources report that PBM clients typically receive 70-90% of rebates).

⁴⁴ FTC report at 60. CMS made a similar point in a recent "call letter" to Medicare Part D plans; CMS stated there that "[w]e must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, i.e., the sponsor receives a price concession from the PBM." CMS PDP Call Letter April 3, 2006, at 10.

As noted earlier, PBMs also establish networks of retail and mail-order pharmacies where patients with PBM-administered benefits can fill prescriptions, and negotiate the reimbursement rates network pharmacies receive (*i.e.*, the total payment the pharmacy receives, including the PBM payment and the patient copayment or coinsurance amount). These negotiated reimbursement rates are lower than the rates that pharmacies charge to uninsured “cash-paying” patients, and usually vary depending on the restrictiveness of the pharmacy network (*i.e.*, pharmacies can obtain more business by participating in a more exclusive network, and may thus be willing to accept lower reimbursement rates).⁴⁵ The drug (“ingredient cost”) reimbursement rates negotiated between PBMs and network pharmacies reportedly are often based on a discount from Average Wholesale Price for brand-name drugs and a Maximum Allowable Cost limitation for generics;⁴⁶ pharmacies usually also receive a dispensing fee. The amount that the PBM itself is reimbursed by its clients may or may not equal the amount paid by the PBM to the pharmacy (*i.e.*, ingredient cost plus dispensing fee minus patient copay/coinsurance); the PBM may be paid for pharmacy costs based on a contractually-specified pharmacy reimbursement rate, and could thus experience a profit or loss on pharmacy costs.⁴⁷

The amount paid to the pharmacy by a patient depends on whether the patient is insured. Patients with insurance pay the copayment or coinsurance amount set by their insurer for the drug in question; uninsured patients usually would pay the “cash price.”⁴⁸ By one estimate, the cash price is approximately 15% higher than the pharmacy’s total payment (*i.e.*, insurance payment plus patient copay) for an insured patient.⁴⁹ Of course, insured patients ordinarily pay a premium for their coverage as well as the payments they make on prescriptions.

Although this brief overview of the pharmaceutical payment system cannot catalogue all of the system’s complexities, it suggests that the “price” of a pharmaceutical product is not easily captured and will depend on the perspective one wishes to examine. Rather than being a single number, the average “price” for a product at a particular time may vary depending on whether one examines the amount realized by the manufacturer; the amount paid by wholesalers; the amount paid by pharmacies; the amount paid by PBMs; the amount paid by PBM clients such as insurers or other health plan sponsors; or the amount paid by patients.

⁴⁵ FTC report at 5; PricewaterhouseCoopers report at 57, 70.

⁴⁶ PricewaterhouseCoopers report at 86-87; FTC report at 4-5; Follow the Pill at 19.

⁴⁷ PricewaterhouseCoopers report at 71; FTC report at 9-10.

⁴⁸ Patients with traditional indemnity insurance also may pay the cash price at the pharmacy counter and then submit a claim for reimbursement to their insurer.

⁴⁹ HHS report at 96.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

RECEIVED

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OFFICE OF INSPECTOR
GENERAL**TO:** Daniel R. Levinson
Inspector General**FROM:** Mark B. McClellan, M.D., Ph.D.
Administrator

A handwritten signature in black ink, appearing to read "Mark McClellan".

SUBJECT: Office of Inspector General (OIG) Draft Report: "Determining Average
Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act
of 2005" (A-06-06-00063)

Thank you for the opportunity to comment on the above draft report. This report looks at the manner in which the Medicaid average manufacturer price (AMP) is determined for drugs under the Deficit Reduction Act of 2005 (DRA).

As discussed in this report, the provisions of the DRA affected not only the Medicaid drug rebate program, but Medicaid reimbursement for drugs, as well. The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers. The DRA requires the OIG to review the requirements for and manner in which AMP is determined and recommend changes to the Secretary by June 1, 2006. The DRA also requires the Secretary to clarify the requirements for and the manner in which AMPs are to be determined by publishing a regulation no later than July 1, 2007.

Prior to the enactment of the DRA, AMP under the Medicaid program has been used solely to calculate drug manufacturer rebates. The DRA allows AMP to be used as a basis for reimbursement. States may use the publicly available AMP in setting their payment methodologies for retail pharmacies. The Centers for Medicare & Medicaid Services (CMS) will use the information to set Federal upper limits (FULs) on payments for multi-source drugs.

The OIG based its recommendations on information gathered through prior investigations. It also met with staff from CMS, Congressional staff, and stakeholder groups and analyzed written comments from six of the stakeholder groups.

OIG Findings and Recommendation

The OIG found that existing requirements for determining certain aspects of AMPs are not clear and comprehensive and that manufacturers' methods of calculating AMPs are inconsistent. While the OIG notes the history of CMS actions in clarifying the definition of AMP and recommends that CMS should consider further modification, it does not recommend a specific definition of AMP.

Page 2- Daniel R. Levinson

Recommendations: The OIG recommends that CMS clarify requirements related to retail class of trade, the treatment of rebates to pharmacy benefit managers (PBMs), and the treatment of Medicaid sales. In addition, the OIG recommends that CMS consider addressing other issues that were raised by industry groups, specifically, administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMP. Finally, the report recommends that CMS issue guidance in the near future addressing the implementation of the AMP-related reimbursement provisions of the DRA and encourage States to analyze the relationship between AMP and pharmacy acquisition cost when using this data source to determine payment rates to pharmacies.

CMS Response to Findings

The CMS acknowledges that the OIG has reported some confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP. This is an extremely complex and technical topic that has been made more difficult due to changes in the chain of sales and the evolution of new entities, especially PBMs. For this reason, CMS had hoped that the OIG would have provided more specific recommendations for us to consider as we develop a proposed rule to address this topic. However, we appreciate the efforts of the OIG in the past, as well as this report, and we look forward to continuing to work with the OIG on this important issue.

CMS Response to Final Recommendation

In our proposed regulation to implement the AMP and reimbursement provisions of the DRA, CMS will take the opportunity to address each of the areas recommended by the OIG in this report as well as each of the areas raised by the stakeholders in the meetings with the OIG and subsequent written comments. We will issue the Notice of Proposed Rulemaking as expeditiously as possible. Likewise, we will review and respond quickly to public comments on the regulation, so that a final rule can be put in place as soon as possible. CMS will evaluate the need for additional guidance and provide this as we believe it would be beneficial.

Attachment

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months						
Measure:	Percentage of cases closed						
Tasks:	1. Mediate all complaints within 90 days (for cases closed during quarter)						
		<u>N</u>	<u>< 90 days</u>	<u>< 120 days</u>	<u>< 180 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	141	113	5	11	12	50
			(81%)	(3%)	(8%)	(8%)	
	Qtr 2	72	67	0	4	1	17
			(94%)	(0%)	(5%)	(1%)	
	2. Investigate all cases within 120 days (for cases closed during quarter)						
		<u>N</u>	<u>< 120 days</u>	<u>< 180 days</u>	<u>< 270 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	271	195	49	25	2	87
			(72%)	(18%)	(9%)	(1%)	
	Qtr 2	173	146	15	12	0	79
			(84%)	(9%)	(7%)	(0%)	
	3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.						
	Qtr 1	<u>N</u>	<u>< 180</u>	<u>< 270</u>	<u>< 365</u>	<u>> 365</u>	
	Closed, no additional action	210	166	14	15	15	
	Cite and/or fine letter of admonishment	167	82	50	25	10	
	Attorney General's Office	35	11	7	10	7	
Qtr 2	<u>N</u>	<u>< 180</u>	<u>< 270</u>	<u>< 365</u>	<u>> 365</u>		
Closed, no additional action	104	94	6	3	1		
Cite and/or fine letter of admonishment	128	33	84	6	5		
Attorney General's Office	12	2	4	3	3		

Objective 1.2	Manage enforcement activities for achievement of performance expectations.						
Measure:	Percentage compliance with program requirements.						
Tasks:	1. Administer the Pharmacists Recovery Program.						
		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program		
	Qtr 1	26	50	1	1		
	Qtr 2	30	54	0	4		
	2. Administer the Probation Monitoring Program.						
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
	Individuals	107	100				
	Sites	5	6				
	Tolled	27	27				
	Inspections Conducted	92	41				
	Successfully Completed	1	1				
	Petitions to Revoke Filed	3	0				
	3. Issue all citations and fines within 30 days						
		N	30 days	60 days	90 days	> 90 days	Average Days
	Qtr 1	140	41 (29%)	61 (43%)	21 (15%)	17 (12%)	51
	Qtr 2	118	14 (12%)	22 (18%)	41 (35%)	41 (35%)	84
	4. Issue letters of admonishment within 30 days						
		N	30 days	60 days	90 days	> 90 days	Average
	Qtr 1	33	30 (91%)	1 (3%)	2 (6%)	0 (0%)	12
	Qtr 2	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	18
	5. Obtain immediate public protection sanctions for egregious violations.						
		Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction			
	Qtr 1	0	0	2			
	Qtr 2	0	0	1			
	6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.						
		30 days	60 days	> 60 days	N		
	Qtr 1	1	0	2	3		
	Qtr 2	0	0	0	0		

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011
Measure:	The number of issues
Tasks:	<ol style="list-style-type: none"> 1. Monitor the implementation of e-pedigree on all prescription medications sold in California. <ul style="list-style-type: none"> <i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i> <i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i> <i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.</i> <i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i> <i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i> 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products. <ul style="list-style-type: none"> <i>Sept. 2006: Final phase-in of federal requirements takes effect on 9/30. Board newsletter provides information for licensees.</i> <i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its Website.</i> 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances. <ul style="list-style-type: none"> <i>Sept. 2006: DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.</i> <i>Oct. 2006: Board considers proposed rule.</i> <i>Nov. 2006: Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i>